UNITED STATES NUCLEAR REGULATORY COMMISSION

Rules and Regulations

This package contains the 1985 Compilation of NRC Rules and Regulations. This Compilation includes the Supplementary material for June and July 1985 and supersedes the 1982 Compilation and its 33 Supplements. Combined Supplements for August and September 1985 will be issued in October.

UNITED STATES NUCLEAR REGULATORY COMMISSION

Rules and Regulations

Title 10 – Chapter 1
CODE of FEDERAL REGULATIONS

CODIFIED AND REISSUED SEPTEMBER 1982

(includes all amendments through July 31, 1985)

Division of Rules and Records
Office of Administration

UNITED STATES NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555

EXPLANATION

This three-volume loose-leaf set contains all Rules and Regulations, Policy Statements, Memoranda of Understanding, listings of Regulatory Guides, and brief summaries of selected General Notices issued by the Nuclear Regulatory Commission (NRC) and other agencies and published in the Federal Register (FR). These volumes are updated monthly in a series of sequentially numbered supplements. Each page of the supplement has a date in the lower outer corner indicating when the page was last updated or had material rearranged on it (reset).

The Rules and Regulations are arranged by subject matter into tabbed and numbered CFR parts. Each numbered part contains all effective or final rules followed by the proposed rules, petitions for rulemaking, and statements of consideration (preambles) published for that part. The references in the margins of the effective rule section are Federal Register citations that indicate the Federal Register volume and page on which the rule was published. The year of publication can be figured by a simple calculation. Subtract 1935–the first year the FR was published–from the current year to get the volume number for the citation. For example, notices published in the Federal Register in 1985 will be cited 50 FR xxxx. There are also brackets and double arrows that can be found in the margins. The brackets indicate the source of amendments to the original text. The brackets may continue from one column to another but will have a wing where the amendment begins (⌈) and another where it ends (⌊). A double arrow (≫) in the margin indicates the most recent amendment on a page.

Questions or comments concerning the material contained in these volumes may be directed to the Rules and Procedures Branch, Division of Rules and Records on their national toll free number (800) 368-5642.

UNITED STATES NUCLEAR REGULATORY COMMISSION
RULES and REGULATIONS
TITLE 10, CHAPTER 1, CODE OF FEDERAL REGULATIONS — ENERGY

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In order to keep your book up to date, please keep this page with your "NRC Rules and Regulations" book and record the dates supplements are received and filed. If you miss a supplement or have other questions concerning distribution, please contact the Customer Service Section, Government Printing Office (202) 275-2060/2171, or write Superintendent of Documents, U.S. Goverment Printing Office, CIB-SSOS, UCP, Washington, D.C. 20401.

MATERIALS INCORPORATED INTO 10 CFR PARTS 0-199 BY REFERENCE

46 FR 63478
Published 12/31/81
Effective 12/31/81

OFFICE OF THE FEDERAL REGISTER

1 CFR Part 51 and CFR Titles 7, 9, 10, 12, 13, 14, 16, and 46

Approval of Incorporations by Reference

AGENCY: Office of the Federal Register.

ACTION: Approval of incorporations by reference and corrections.

SUMMARY: The Office of the Federal Register publishes a document listing materials that have been approved by the Director for incorporation by reference. The document also corrects a previously published listing.These references appear in Titles 7 through 16 and 46 of the *Code of Federal Regulations* (CFR). This document is published to inform the public of materials that have the Director's approval and have the same legal status as if they were published in full text in the Federal Register.

EFFECTIVE DATE: The Director approves the following incorporations by reference for one year effective January, 1, 1982, unless otherwise noted.

ADDRESSES: For specific addresses where materials are available, see table. Materials are also on file at the Office of the Federal Register, 1100 L Street, NW, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Joan F. Montgomery, (202) 523-4534.

SUPPLEMENTARY INFORMATION:

Background. Each agency that wishes material incorporated by reference to remain effective must annually submit to the Director a list of that material and the date of its last revision (1 CFR 51.13). The materials included on the table below are incorporated by reference under 5 U.S.C. 552(a) and 1 CFR Part 51. These procedures provide that material approved for incorporation by reference by the Director of the Federal Register has the same legal status as if it were published in full text in the Federal Register.

Availability. Before an agency may incorporate by reference any material, it must make the material reasonably available to the class of persons affected by it. Agencies have listed addresses where you can obtain each item included in the table. The materials approved for incorporation by reference are also available for inspection and copying at the Office of the Federal Register, Room 8401, 1100 L St., NW, Washington, DC, phone (202) 523-5240.

Amendments. If the agency wishes to amend material before the annual approval expires, the agency shall publish a notice which announces the amendment and states where the material may be obtained. The agency shall also assure that the material and its amendments are available to the public and on file at the Office of the Federal Register. Unless the agency follows these procedures, the amendments are not approved.

Quarterly Publication. The titles of the CFR are generally revised according to the following schedule:

Title 1 through Title 16—as of January 1.

Title 17 through Title 27—as of April 1.

Title 28 through Title 41—as of July 1.

Title 42 through Title 50—as of October 1.

Every quarter, the Office of the Federal Register publishes a document on incorporation by reference. This quarterly document contains the following information on incorporation by reference. First, it contains a table of materials in the applicable titles that have been reapproved for incorporation by reference under 1 CFR 51.13. Second, the document contains a listing of any materials which were granted extensions under 1 CFR 51.13 review in the last quarter and have since received final approval by the Director of the Federal Register. And third, the document may contain corrections to previously published incorporation by reference approval documents.

Material which is approved in a timely fashion during the quarterly review process is also listed in the appropriate *Code of Federal Regulations* volume(s).

How the Table is Arranged. The table is arranged first by headings indicating the CFR title and chapter and the name of the agency incorporating the material. Under each of these headings are listed the name of the standards producing organization, a description of the material being incorporated and where it is available, and the CFR part or section where the material is referenced.

Problems. If you have any problems obtaining the material, notify the agency. If you find the material is not available, notify the Director of the Federal Register (NARS), Washington, DC 20408 or call (202) 523-4534.

John E. Byrne,
Director of the Federal Register.

MATERIALS INCORPORATED INTO 10 CFR PARTS 0-199 BY REFERENCE

10 CFR CHAPTER I (PARTS 0 TO 199)
NUCLEAR REGULATORY COMMISSION

Each of the following documents is available for inspection at the Nuclear Regulatory Commission's Library, 7920 Norfolk Ave., Bethesda, MD. The individual documents are available through the sources listed below.

	10 CFR
American Association of Physicists in Medicine 335 E. 45th St., New York, NY 10017	
Scientific Committee on Radiation Dosimetry of the American Association of Physicists in Medicine, Physics in Medicine and Biology, Volume 16, No. 3, 1971, 379–398.	35.21(c)
American National Standards Institute 1430 Broadway, New York, NY 10018	
ASA B31.1 1955 Edition, American Standard Code for Pressure Piping	50.55a
USAS B31.1.0 1967 Edition, Addenda A, B & C, U.S.A. Standard Code for Pressure Piping	50.55a
USAS B31.7 1969 Edition, Addenda A, B & C, U.S.A. Standard Code for Pressure Piping	50.55a
ANSI N45.4–1972 Leakage Rate Testing of Containment Structures for Nuclear Reactors, March 16, 1972	Part 50, App. J, III.A.3.a
ANSI MH5.1–1971 Basic Requirements for Cargo Containers (1971)	73.26
ANSI S3.6–1969 (R 1973) Specifications for Audiometers	Part 73, App. B, I.B.b(2)
International Standards Organization (ISO) 1496–1978 General Cargo Containers	73.26
International Standards Organization (ISO) 389–1975 Standard Reference Zero for the Calibration of Puretone Audiometer.	Part 73, App. B, I.B.b(2)
American Nuclear Society 555 North Kensington Ave., La Grange Park, IL 60525	
Proposed American Nuclear Society Standard—Decay Energy Release Rates Following Shutdown of Uranium Fueled Thermal Reactors, Approved by Subcommittee ANS–5, ANS Standards Committee, October 1971.	Part 50, App K, I.A.4
American Society of Mechanical Engineers United Engineering Center, 345 East 47th St., New York, NY 10017	
ASME Boiler and Pressure Vessel Code Section III 1963 Edition: Addenda Summer 64; Winter 64 1965 Edition: Addenda Summer 65; Winter 65; Summer 66; Winter 66; Summer 67; Winter 67 1968 Edition: Addenda Summer 68; Winter 68; Summer 69; Winter 69; Summer 70; Winter 70 1971 Edition: Addenda Summer 71; Winter 71; Summer 72; Winter 72; Summer 73; Winter 73	50.55a
ASME Boiler and Pressure Vessel Code Section III, Division 1 1974 Edition: Addenda Summer 74; Winter 74; Summer 75; Winter 75; Summer 76; Winter 76 1977 Edition: Addenda Summer 77; Winter 77; Summer 78; Winter 78; Summer 79; Winter 79 1980 Edition: Addenda Summer 80; Winter 80	50.55a
ASME Boiler and Pressure Vessel Code Section XI, Division 1 1970 Edition: Addenda Winter 70 1971 Edition: Addenda Summer 71; Winter 71; Summer 72; Winter 72; Summer 73; Winter 73 1974 Edition: Addenda Summer 74; Winter 74; Summer 75; Winter 75; Summer 76; Winter 76 1977 Edition: Addenda Summer 77; Winter 77; Summer 78; Winter 78; Summer 79; Winter 79 1980 Edition: Addenda Winter 80	50.55a
Draft ASME Code for Pumps and Valves for Nuclear Power, dated November 1968 and 1 addenda dated 1970	50.55a
F. J. Moody, Maximum Flow Rate of a Single Component, Two-Phase Mixture, Journal of Heat Transfer, Trans American Society of Mechanical Engineers, 87, No. 1, February 1965.	Part 50, App. K, I.C.1.b.
American Society for Testing Materials (ASTM) 1916 Race St., Philadelphia, PA 19103	
ASTM E 185–73 and E 185–79 Standard Recommended Practice for Surveillance Tests for Nuclear Reactor Vessels	Part 50, App. H, II.B

MATERIALS INCORPORATED INTO 10 CFR 0-199 BY REFERENCE

10 CFR CHAPTER I (PARTS 0 TO 199)—Continued
NUCLEAR REGULATORY COMMISSION—Continued

	10 CFR
Commerce Department, National Technical Information Service	
5285 Port Royal Road, Springfield, VA 22161	
Baker-Just, Studies of Metal Water Reactions at High Temperatures, III. Experimental and Theoretical Studies of the Zirconium-Water Reaction, ANL-6548, page 7, May 1962.	Part 50, App. K, I.A.5
PWR FLECHT (Full Length Emergency Cooling Heat Transfer) Final Report, Westinghouse Report WCAP-7665, April 1971.	Part 50, App. K, I.D.5
Federal Specifications	
Naval Publications and Forms Center, 5801 Tabor Road, Philadelphia, PA 19120	
GSA Interim Federal Specification W-A-00450B (GSA-FSS): Alarm Systems, Interior, Security, Components For	73.50
General Electric Company	
Nuclear Energy Business Group, Technical Support Services, MC-211, 175 Curtner Ave., San Jose, CA 95125	
Loss-of-Coolant Accident and Emergency Core Cooling Models for General Electric Boiling Water Reactors, General Electric Company Report NEDO-10329, April 1971.	Part 50, App. K, I.D.7.c
Institute of Electrical and Electronic Engineers	
United Engineering Center, 345 East 47th St., New York, NY 10017	
IEEE-279 Criteria for Protection Systems for Nuclear Generating Stations, dated August 30, 1968 and June 3, 1971	50.55a(h)
International Atomic Energy Agency	
Available from: Assistant Director for Export/Import and International Safeguards, Office of International Progams, Nuclear Regulatory Commission, Washington, DC 20555	
IAEA INFCICR/225 Rev. 1, The Physical Protection of Nuclear Material	110.43(a)(1)
National Rifle Association	
Competitions & Training Division, 1600 Rhode Island Ave., NW., Washington, D.C. 20036	
NRA Target Manufacturers Index, December 1976	Part 73, App. B, IV.C.2-a.2
Nuclear Regulatory Commission	
Office of Nuclear Regulatory Research, Washington, D.C. 20555	
NOTE: The following publication is approved for incorporation by reference until Apr. 1, 1982.	
Regulatory Guide 8.15 "Acceptable Programs for Respiratory Protection" Oct. 1976	20.103(c)

≫48 FR 27646
Published 7/16/83

Reader Aids

Federal Register Thesaurus of Indexing Terms

Federal Register Thesaurus of Indexing Terms

1 CFR 18.20 requires Federal agencies to identify major topics and categories of persons affected in their regulations in standard terms from the Federal Register Thesaurus of Indexing Terms. The Thesaurus was last published in the **Federal Register** of February 17, 1981 (46 FR 12616). A revised edition of the Thesaurus is published today for use by agencies and for public information.

Scope

The Federal Register Thesaurus is a basic indexing vocabulary for Federal regulations which are published in the **Federal Register** and the *Code of Federal Regulations.* It includes indexing terms to describe the specific program regulations of individual agencies as well as general administrative regulations common to all agencies. The indexing terms included are intended to express and organize the often technical regulatory concepts in research terms familiar to laypersons.

Use

The Office of the Federal Register uses the Thesaurus as the basis for the subject entries in the *Code of Federal Regulations* Index which is published annually as of January 1. Federal agencies also use the Thesaurus to prepare the "List of Subjects" which is included in rule and proposed rule documents submitted for publication in the **Federal Register**. The Office of the Federal Register selects terms from these agency-compiled subject lists to prepare the "Selected Subjects" which appears on the inside cover of the **Federal Register** daily.

Federal agencies and Office of the Federal Register staff members have suggested a number of additions and/or changes to the Thesaurus during the past two years. Some of these suggestions have been incorporated into this edition of the Thesaurus as indexing terms. Others have been added as cross-references to indexing terms. For the convenience of users a list of indexing terms added since the last printing of the Thesaurus appears below.

Adoption and foster care
Animal biologics
Animal welfare
Bank deposit insurance
Child support
Confidential business information
Countervailing duties
Disability benefits
Equal access to justice
Flood control
Food packaging
Fuel economy
Government publications
Hazardous substances
Hazardous waste
Homeworkers
Hostages
Indians-judgment funds
Indians-tribal government
Lobbying
Pension insurance
Plant diseases and pests
Real property acquisition
Reporting and recordkeeping requirements

Organization

There are two sections to the Thesaurus. The first is an alphabetic list of all indexing terms with a series of notations under each term to refer users to preferred or related terms. The second is a grouping of terms under 19 broad subject categories, allowing the user to determine quickly the existing Thesaurus terms for that broad subject.

Copies

Copies of the Thesaurus are available from the Office of the Federal Register, National Archives and Records Service, Washington, DC 20408.

FOR FURTHER INFORMATION CONTACT: Carol Mahoney, telephone (202) 523–5240.

FEDERAL REGISTER THESAURUS (REVISED)

Accidents
see Safety

Accountants (02, 13)
Accounting (02, 08)
sa Uniform System of Accounts
xx Business and industry

Acreage allotments (01)
xx Agricultural commodities

Additives
see Color additives
Food additives
Fuel additives

Adhesives
Adjustment assistance
see Trade adjustment assistance

Administrative practice and procedure (08)
(Use for hearing, appeal, petition, rulemaking, etc., procedures)
sa Claims
Environmental impact statements
Equal access to justice
Freedom of information
Privacy
Sunshine Act
x Appeal procedures
Ex parte communications
Hearing and appeal procedures
Practice and procedure
xx Law

Adoption and foster care (18)
x Foster care
xx Infants and children

Adult education (04)
x Continuing education
Extension and continuing education
xx Education

Advertising (02)
xx Business and industry

Advisory committees (08)
(Use for management of advisory committees within an agency)
x Committees

AFDC
see Aid to Families with Dependent Children

Affirmative action plans
see Equal employment opportunity

Aged (13)
sa Medicaid
Medicare
Public assistance programs
Supplemental Security Income (SSI)
x Discrimination against aged
Elderly
Senior citizens

Agricultural commodities (01)
(The names of specific agricultural commodities, e.g. Corn, are not listed in this Thesaurus but may be used as indexing terms.)
sa *Specific commmodities*
Acreage allotments
Commodity futures
Crop insurance
Fruits
Grains
Marketing agreements
Marketing quotas
Nuts
Oilseeds
Price support programs
Surplus agricultural commodities
Vegetables
x Commodities
Crops
xx Agriculture

Agricultural research (01, 17)
xx Agriculture
Research

Agriculture (01)
sa Agricultural commodities
Agricultural research
Fertilizers
Food assistance programs
Foods
Forests and forest products
Irrigation
Migrant labor
Pesticides and pests
Range management
Rural areas
x Farmers

Aid to Families with Dependent Children (18)
sa Public assistance programs
Work Incentive Programs (WIN)
x AFDC
xx Child welfare
Infants and children
Public assistance programs
Social security

Air carriers (19)
(Organizations operating passenger or cargo carrying aircraft)
sa Air rates and fares
Air taxis
Charter flights
x Airlines
Foreign air carriers
Shipping
xx Air transportation
Common carriers

Air fares
see Air rates and fares

Air pollution control (06)
sa Motor vehicle pollution
x Clean Air Act
xx Environmental protection

Air rates and fares (19)
x Air fares
Air tariffs
Rates and fares
xx Air carriers
Air transportation

Air safety
see Aviation safety

Air tariffs
see Air rates and fares

Air taxis (19)
xx Air carriers
Air transportation

Air traffic control (19)
xx Air transportation

Air transportation (19)
sa Air carriers
Air rates and fares
Air taxis
Air traffic control
Aircraft
Airmen
Airports
Airspace
Aviation safety
Charter flights
Military air transportation
Navigation (air)
xx Transportation

Aircraft (19)
x Airplanes
Airworthiness directives and standards
Balloons
Helicopters
Kites
Parachutes
Rockets
Rotorcraft
Seaplanes
xx Air transportation

Aircraft pilots
see Airmen

Airlines
see Air carriers

Airmen (13, 19)
x Aircraft pilots
Pilots
xx Air transportation

Airplanes
see Aircraft

Airports (19)
x Heliports
xx Air transportation

Airspace (19)
x Airways
xx Air transportation

See refers to authorized terms; x refers from terms not used; sa refers to more specific or related terms; xx refers from broader or related terms
Number in parenthesis refer to subject category listings following alphabetical listing of terms

Airways
  see Airspace

Airworthiness directives and standards
  see Aircraft

Alaska natives
  see Indians

Alcohol and alcoholic beverages (01)
  sa Beer
    Gasohol
    Liquors
    Wine
  xx Beverages

Alcoholism (09)
  xx Drug abuse

Alien property (07)
Aliens (07, 13)
  sa Citizenship and naturalization
    Immigration
    Refugees
  x Deportation
    Foreign persons
  xx Citizenship and naturalization
    Immigration
    Refugees

Alimony (12)
  sa Child support

Amateur radio service
  see Radio

American Indians
  see Indians

Ammunition
  see Arms and munitions

Anchorage grounds (19)
  sa Harbors
  x Water transportation
  xx Vessels

Animal biologics (01, 09)
  xx Animal drugs
    Biologics

Animal diseases (01, 09)
  x Diseases
  xx Animals

Animal drugs (01, 09)
  sa Animal biologics
  xx Animal feeds
    Animals
    Drugs

Animal feeds (01)
  sa Animal drugs
  xx Animals

Animal foods (01)
  xx Animals
    Foods

Animal welfare (01)
  x Humane treatment of animals
  xx Animals

Animals (01)
  sa Animal diseases
    Animal drugs
    Animal feeds
    Animal foods
    Animal welfare
    Livestock
    Pets
    Wildlife

Annuities
  see Pensions

Antennas
  see Communications equipment

Antibiotics (09)
  xx Drugs

Antidumping (02, 07)
  (Prohibition on sales of imports at less than fair value)
  xx Customs duties and inspection
    Imports

Antiquities
  see Historic preservation

Antitrust (02)
  x Interlocking directorates
    Management official interlocks
  xx Business and industry

Appeal procedures
  see Administrative practice and procedure

Appliances
  see Household appliances

Apprenticeship programs
  see Manpower training programs

Archaeology
  see Historic preservation

Architects (13)
Architectural barriers
  see Handicapped

Archives and records (08)
  sa Classified information
  x Historical records
    Information
    Records

Armed forces (14)
  (Use for general regulations applicable to all services)
  sa *Specific military departments*
    Armed forces reserves
    Conscientious objectors
    Military academies
    Military law
    Military personnel
    Selective service system
  xx National defense

Armed forces reserves (14)
  x National guard
    Reserve forces
  xx Armed forces
    Military personnel

Arms and munitions (14)
  x Ammunition
    Firearms
    Guns
    Military arms sales
    Munitions
    Weapons
  xx National defense

Arms control (07, 14)
  x Disarmament
  xx Foreign relations
    National defense

Art (04)
Arts and crafts (04)
  sa Indians–arts and crafts
  x Crafts
    Handicrafts

Asbestos
Asylum
  see Immigration

Atomic energy
  see Nuclear energy

Attorneys
  see Lawyers

Authority delegations (Government agencies) (08)
  sa Organization and functions (Government agencies)
  xx Organization and functions (Government agencies)

Automatic data processing
  see Computer technology

Automobiles
  see Motor vehicles

Aviation safety (09, 19)
  x Air safety
  xx Air transportation
    Safety

Awards
  see Decorations, medals, awards

Baggage
  see Freight

Bakery products (01)
  x Bread
  xx Foods

Balloons
  see Aircraft

See refers to authorized terms; x refers from terms not used; sa refers to more specific or related terms; xx refers from broader or related terms
Number in parenthesis refer to subject category listings following alphabetical listing of terms

FEDERAL REGISTER THESAURUS (REVISED)

Bank deposit insurance (02)
x Deposit insurance
xx Banks, banking
Insurance

Bankruptcy (02)
xx Business and industry

Banks, banking (02)
sa Bank deposit insurance
Credit
Electronic funds transfers
Federal home loan banks
Federal reserve system
Foreign banking
National banks
Savings and loan associations
Trusts and trustees
x Checks
Finance
xx Credit

Barges
see Cargo vessels

Barrels
see Packaging and containers

Beaches
see Seashores

Beef
see Meat and meat products

Beer (01)
xx Alcohol and alcoholic beverages

Bees (01)
Beverages (01)
sa Alcohol and alcoholic beverages
Coffee
Fruit juices
Tea
Vegetable juices
xx Foods

Bicycles (16, 19)
Bilingual education (04)
xx Education

Biologics (09)
(Viruses, serums, toxins, etc., used in disease treatment)
sa Animal biologics
Blood
x Serums
Toxins
Vaccines
Viruses
xx Drugs

Birds
see Wildlife

Birth control
see Family planning

Black lung benefits (09)
x Pneumoconiosis
xx Health insurance
Lung diseases
Mine safety and health

Blind (09, 13)
sa Medicaid
Public assistance programs
Supplemental Security Income (SSI)
xx Handicapped

Blood (09)
xx Biologics

Blood diseases (09)
x Hemophilia

Boats and boating safety
see Marine safety
Navigation (water)

Bonding
see Surety bonds

Bonds (02)
x Savings bonds
xx Government securities
Securities

Borders
see International boundaries

Boycotts (07)
Bread
see Bakery products

Bridges (19)
x Drawbridges
xx Highways and roads
Transportation
Waterways

Broadcasting
see Radio
Television

Brokers (02, 13)
xx Investments

Buildings (10)
sa Federal buildings and facilities

Buses (19)
sa Motor carriers
Motor vehicles
x Charter buses
xx Motor carriers
Motor vehicles

Business and industry (02)
(The names of specific industries, e.g. Construction industry, are not listed in this Thesaurus but may be used as indexing terms. For a standard list of industry names we recommend using the *Standard Industrial Classification Manual.*)
sa *Specific industries*
Accounting
Advertising
Antitrust
Bankruptcy
Concessions
Confidential business information
Holding companies
Indians-business and finance
Labeling
Labor
Minority businesses
Packaging and containers
Relocation assistance
Small businesses
Taxes
Trade adjustment assistance
Trade names
Trade practices
Trademarks
Warranties
x Corporations
Industry

Butter (01)
sa Margarine

Cable television (03)
x Community antenna television systems
xx Television

Cacao products (01)
x Chocolate
Cocoa
xx Foods

Campaign funds (08)
x Election finance
xx Elections
Political candidates

Cancer (09)
Candy (01)
x Confectionery
xx Foods

Cargo
see Freight

Cargo vessels (19)
sa Maritime carriers
x Barges
Tank vessels
xx Maritime carriers
Vessels

Carpets and rugs
x Rugs

See refers to authorized terms; x refers from terms not used; sa refers to more specific or related terms; xx refers from broader or related terms
Number in parenthesis refer to subject category listings following alphabetical listing of terms

FEDERAL REGISTER THESAURUS (REVISED)

Carpools (19)
x Vanpools
xx Highways and roads
Motor vehicles

Cemeteries
x National cemeteries

Census data (08)
x Population census
xx Statistics

Cereals (commodity)
see Grains

Cereals (food) (01)
xx Foods

Chaplains (13)
Charter buses
see Buses

Charter flights (19)
xx Air carriers
Air transportation

Checks
see Banks, banking

Chemicals (01, 09)
(The names of specific chemicals are not listed in this Thesaurus but may be used as indexing terms.)
sa *Specific chemicals*
Drugs
Fertilizers
Hazardous substances
Pesticides and pests

Child abuse
see Child welfare

Child health
see Maternal and child health

Child labor (11, 13)
xx Child welfare
Labor

Child support (18)
xx Alimony
Child welfare

Child welfare (18)
sa Aid to Families with Dependent Children
Child labor
Child support
Day care
Maternal and child health
x Child abuse
xx Infants and children
Public assistance programs
Social security

Children
see Infants and children

Chocolate
see Cacao products

Cigars and cigarettes (01)
sa Smoking
xx Tobacco

Citizens band radio service
see Radio

Citizenship and naturalization (07)
sa Aliens
Immigration
x Nationality
Naturalization
Repatriation
xx Aliens
Foreign relations
Immigration

Citrus fruits (01)
sa *Specific fruits*
xx Fruits

Civil defense (14)
sa Disaster assistance
x Emergency mobilization
xx Disaster assistance
National defense

Civil disorders (12)
Civil rights (12)
sa Equal educational opportunity
Equal employment opportunity
Fair housing
Religious discrimination
Sex discrimination
Voting rights
x Discrimination
Minority groups
Nondiscrimination

Civil service system
see Government employees

Claims (12)
sa Foreign claims
Indians–claims
War claims
x Tort claims
xx Administrative practice and procedure

Classified information (14)
x Declassification
Information
Intelligence
National security information
Security information
xx Archives and records
National defense
Security measures

Clean Air Act
see Air pollution control

Clemency (12)
x Pardon

Clothing (02)
sa Footwear

Coal (05)
sa Coal conversion program
xx Energy
Mineral resources

Coal conversion program (05)
xx Coal

Coal miners
see Miners

Coal mines
see Mine safety and health
Mines
Surface mining
Underground mining

Coastal zone (15)
sa Continental shelf
Flood plains
Seashores
x Estuaries
Wetlands
xx Natural resources
Seashores

Cocoa
see Cacao products

Coffee (01)
xx Beverages

Coin operated machines
Coins
see Currency

Collective bargaining
see Labor management relations

Colleges and universities (04)
sa Medical and dental schools
Military academies
Student aid
x Community colleges
Higher education
Universities
xx Education
Schools

Color additives (01, 09)
x Additives
xx Food additives

Commercial fisheries
see Fisheries

Committees
see Advisory committees

Commodities
see Agricultural commodities

Commodity futures (01, 02)
xx Agricultural commodities
Investments

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Common carriers (02, 19)
sa Air carriers
Communications common carriers
Freight forwarders
Maritime carriers
Motor carriers
Railroads
xx Transportation

Communicable diseases (09)
x Contagious diseases

Communications (03)
sa Communications common carriers
Communications equipment
Defense communications
Motion pictures
News media
Recordings
Telecommunications

Communications common carriers (02, 03)
x Rates and fares
xx Common carriers
Communications

Communications equipment (03)
x Antennas
xx Communications

Communist countries (07)
sa *Specific countries*

Community action programs (18)
(Financial assistance to local communities to provide basic antipoverty services)
x Poverty
xx Community development

Community antenna television systems
see Cable television

Community colleges
see Colleges and universities

Community development (10)
(Economic development of deprived areas, emphasizing improved living conditions and participation of the local population.)
sa Community action programs
Urban renewal
x Economic development
Unemployment
xx Urban renewal

Community development block grants (10)
Community facilities (10)
sa Health facilities
x Public works

Compensation
see Indemnity payments
Unemployment compensation
Wages
Workers' compensation

Comprehensive Employment and Training Act
see Manpower training programs

Computer technology (17)
x Automatic data processing
Data processing
Electronic data processing

Concessions (02)
xx Business and industry

Condominiums (10)
xx Housing

Conduct standards
see Conflict of interests

Confectionery
see Candy

Confidential business information (02)
x Information
xx Business and industry
Freedom of information
Privacy

Conflict of interests (08)
sa Political activities (Government employees)
x Conduct standards
Ethical conduct
Financial disclosure
xx Government employees

Congressional elections
see Elections

Conscientious objectors (13, 14)
xx Armed forces

Conservation
see Energy conservation
Natural resources

Consular services
see Foreign Service

Consultants (13)
Consumer protection (02)
sa Labeling
Trade practices
Truth in lending
xx Safety

Contagious diseases
see Communicable diseases

Containers
see Packaging and containers

Continental shelf (15)
x Offshore structures
Outer continental shelf
xx Coastal zone
Natural resources

Continuing education
see Adult education

Contracts
see Government contracts

Controlled substances
see Drug traffic control

Cooperative agreements
see Grant programs

Cooperatives
Copyright (12)
x Royalties

Corporations
see Business and industry

Cosmetics (09)
x Toiletries

Cottonseeds (01)
xx Oilseeds

Counterfeiting (12)
xx Crime

Countervailing duties (02, 07)
(Duties on sales of subsidized imports)
xx Customs duties and inspection
Imports

Courts (12)
xx Law

Crafts
see Arts and crafts

Credit (02)
sa Banks, banking
Credit unions
Mortgages
Truth in lending
x Debts
Equal credit opportunity
Finance
xx Banks, banking

Credit unions (02)
xx Credit

Crime (12)
sa Counterfeiting
Drug abuse
Forgery
Fraud
Juvenile delinquency

Crime insurance (02)
xx Insurance

Crop insurance (01, 02)
xx Agricultural commodities
Insurance

Crops
see Agricultural commodities

Crude oil
see Petroleum

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FEDERAL REGISTER THESAURUS (REVISED)

Cultural exchange programs (04, 07)
x Exchange visitor program
xx Foreign relations

Currency (02)
sa Foreign currencies
Gold
Silver
x Coins
Finance
Foreign exchange
Money

Customs duties and inspection (02, 07)
sa Antidumping
Countervailing duties
Imports
x Tariffs
xx Foreign trade
Imports
Taxes

Dairy products (01)
(The names of specific dairy products, e.g. Cheese, are not listed in this Thesaurus but may be used as indexing terms.)
sa *Specific dairy products*
xx Foods

Dams (15)
xx Flood control
Water supply

Dangerous cargo
see Hazardous materials transportation

Data processing
see Computer technology

Day care (18)
xx Child welfare

Deaf
see Handicapped

Debts
see Credit

Declassification
see Classified information

Decorations, medals, awards (08)
x Awards
Medals

Deepwater ports
see Harbors

Defense
see National defense

Defense acquisition regulations
see Government procurement

Defense communications (03, 14)
xx Communications
National defense

Defense contracts
see Government contracts
Government procurement

Deliquency
see Juvenile delinquency

Dental health (09)
xx Health

Dental schools
see Medical and dental schools

Deportation
see Aliens

Deposit insurance
see Bank deposit insurance

Desegregation in education
see Equal educational opportunity

Dietary foods (01)
xx Foods

Disability benefits (11)
(Use for insurance and retirement benefits provided for individuals unable to work)
sa Railroad retirement
Workers' compensation
x Disabled
xx Handicapped

Disabled
see Disability benefits
Handicapped
Medicaid
Medicare
Public assistance programs
Supplemental Security Income (SSI)

Disarmament
see Arms control

Disaster assistance (08)
sa Civil defense
Emergency medical services
x Drought assistance
Floods
xx Civil defense

Discrimination
see Civil rights

Discrimination against aged
see Aged

Discrimination against handicapped
see Handicapped

Discrimination in education
see Equal educational opportunity

Discrimination in employment
see Equal employment opportunity

Discrimination in housing
see Fair housing

Diseases
(The names of specific diseases, with some exceptions, are not listed in this Thesaurus but may be used as indexing terms.)
see *Specific diseases*
Animal diseases

Distilled spirits
see Liquors

Diving
Doctors
see Health professions

Domestic animals
see Livestock

Draft
see Selective service system

Drawbridges
see Bridges

Drinking water
see Water supply

Drought assistance
see Disaster assistance

Drug abuse (09)
sa Alcoholism
xx Crime
Health

Drug traffic control (12)
x Controlled substances
Narcotics
xx Law enforcement

Drugs (09)
(The names of specific drugs are not listed in this Thesaurus but may be used as indexing terms.)
sa *Specific drugs*
Animal drugs
Antibiotics
Biologics
Over-the-counter drugs
Prescription drugs
xx Chemicals
Health

Eavesdropping
see Wiretapping and electronic surveillance

Ecology
see Environmental protection

Economic development
see Community development

Economic statistics (02)
x Economics
xx Statistics

Economics
see Economic statistics
Price controls

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Education (04)
sa Adult education
Bilingual education
Colleges and universities
Education of disadvantaged
Education of handicapped
Educational facilities
Educational research
Educational study programs
Elementary and secondary education
Equal educational opportunity
Indians-education
Libraries
School breakfast and lunch programs
School construction
Schools
Student aid
Students
Teachers
Vocational education

Education of disadvantaged (04)
x Follow Through Program
Head Start Program
Upward Bound Program
xx Education

Education of handicapped (04)
xx Education
Handicapped

Educational facilities (04)
xx Education
Schools

Educational research (04, 17)
xx Education
Research

Educational study programs (04)
(Use for particular areas of study, e.g. Reading, Foreign languages)
xx Education

Elderly
see Aged

Election finance
see Campaign funds

Elections (08)
sa Campaign funds
Political activities (Government employees)
Political candidates
Political committees and parties
Voting rights
x Congressional elections
Presidential elections

Electric power (05)
sa Electric power plants
Electric power rates
Electric utilities
x Hydroelectric power
xx Energy

Electric power plants (05)
xx Electric power

Electric power rates (05)
x Rates and fares
xx Electric power

Electric utilities (05)
x Public utilities
xx Electric power
Utilities

Electronic data processing
see Computer technology

Electronic funds transfers (02)
xx Banks, banking

Electronic products (17)
Electronic surveillance
see Wiretapping and electronic surveillance

Elementary and secondary education (04)
x Secondary education
xx Education

Emergency medical services (09)
xx Disaster assistance
Health care

Emergency mobilization
see Civil defense

Emergency powers (08, 14)
(Extraordinary authority delegated to the Executive in time of national emergency)
xx National defense

Employee benefit plans (11)
(Various plans established by employers to provide financial protection to employees against accidents, illness, death; or to provide certain services such as training, day care, etc.)
sa Pensions
x Fringe benefits
xx Labor
Wages

Employee management relations
see Labor management relations

Employee Retirement Income Security Act
see Pensions

Employment (11)
sa Equal employment opportunity
Government employees
Manpower
xx Labor

Employment taxes (02)
xx Taxes

Endangered and threatened wildlife (15)
xx Wildlife

Energy (05)
sa Coal
Electric power
Energy conservation
Geothermal energy
Natural gas
Nuclear energy
Petroleum
Pipelines
Solar energy
x Fuel
Power resources
xx Natural resources

Energy conservation (05)
sa Fuel economy
x Conservation
xx Energy

Engineers (13)
Environmental impact statements (06)
xx Administrative practice and procedure
Environmental protection

Environmental protection (06)
sa Air pollution control
Environmental impact statements
Natural resources
Noise control
Pesticides and pests
Reclamation
Waste treatment and disposal
Water pollution control
x Ecology
Pollution
xx Natural resources

Equal access to justice (08)
xx Administrative practice and procedure

Equal credit opportunity
see Credit

Equal educational opportunity (04, 12)
x Desegregation in education
Discrimination in education
School integration
Segregation in education
xx Civil rights
Education

Equal employment opportunity (11, 12)
x Affirmative action plans
Discrimination in employment
xx Civil rights
Employment
Labor

Eskimos
see Indians

Estate taxes (02)
xx Taxes

Estates (02)
Estuaries
see Coastal zone

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Ethical conduct
see Conflict of interests

Ex parte communications
see Administrative practice and procedure

Exchange visitor program
see Cultural exchange programs

Excise taxes (02)
x Stamp taxes
xx Taxes

Executive orders (08)
xx Presidential documents

Explosives (09)
sa Hazardous materials transportation
Hazardous substances
xx Hazardous substances

Exports (02, 07)
xx Foreign trade

Expositions
see Fairs and expositions

Extension and continuing education
see Adult education

Fabrics
see Textiles

Fair housing (10, 12)
x Discrimination in housing
xx Civil rights
Housing

Fairs and expositions (02, 07)
x Expositions
International expositions
Trade fairs
xx Foreign trade

Fallout shelters (14)
Family health
see Maternal and child health

Family planning (09, 18)
x Birth control
Population control
Sterilization
xx Health

Farmers
see Agriculture

Fats and oils
see Oils and fats

Federal aid programs
see Grant programs
Indemnity payments
Loan programs
Price support programs
Technical assistance

Federal buildings and facilities (08)
x Government buildings
Military installations
Public buildings
xx Buildings
Government property

Federal employees
see Government employees

Federal home loan banks (02)
xx Banks, banking

Federal Prison Industries (12)
xx Prisons

Federal procurement regulations
see Government procurement

Federal property management regulations
see Government property management

Federal reserve system (02)
xx Banks, banking

Federal–State relations
see Intergovernmental relations

Federally affected areas (08)
(Use for local jurisdictions, especially school districts, financially burdened by serving Federal installations in the area)
x Impacted areas programs

Feed grains (01)
xx Grains

Fellowships
see Scholarships and fellowships

Fertilizers (01)
xx Agriculture
Chemicals

Films
see Motion pictures

Finance
see Banks, banking
Credit
Currency
Indians-business and finance
Investments
Loan programs
Mortgages
Revenue sharing
Trusts and trustees

Financial disclosure
see Conflict of interests

Fines and penalties
see Penalties

Fire prevention (09)
xx Safety

Firearms
see Arms and munitions

Firefighters (13)
Fish (15)
(Use for conservation, etc., of fish as marine life. Use Seafood for documents on fish as food)
sa Fisheries
Seafood
xx Natural resources
Seafood

Fisheries (15)
(Use for commercial fishing)
x Commercial fisheries
xx Fish
Marine resources
Seafood

Fishing (16)
(Use for sport fishing)
x Recreational fishing
Sport fishing
xx Recreation and recreation areas

Fishing vessels (19)
xx Vessels

Flags (08)
Flammable materials (09)
xx Hazardous substances

Flavorings
see Spices and flavorings

Flaxseeds
see Oilseeds

Flood control (15)
sa Dams
Reservoirs

Flood insurance (02)
xx Insurance

Flood plains (15)
x Wetlands
xx Coastal zone

Floods
see Disaster assistance

Follow Through Program
see Education of disadvantaged

Food additives (01)
sa Color additives
x Additives
Food ingredients
Generally Recognized as Safe (GRAS) food ingredients
xx Foods

Food assistance programs (01, 18)
sa Food stamps
School breakfast and lunch programs
x Poverty
xx Agriculture
Foods
Nutrition

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Food grades and standards (01)
sa Meat inspection
x Food inspection
xx Foods

Food ingredients
see Food additives

Food inspection
see Food grades and standards

Food labeling (01)
xx Foods
Labeling

Food packaging (01)
xx Foods
Packaging and containers

Food stamps (01, 18)
xx Food assistance programs

Foods (01)
(The names of specific foods are not listed in this Thesaurus but may be used as indexing terms.)
sa *Specific foods*
Animal foods
Bakery products
Beverages
Cacao products
Candy
Cereals (food)
Dairy products
Dietary foods
Food additives
Food assistance programs
Food grades and standards
Food labeling
Food packaging
Frozen foods
Fruits
Meat and meat products
Nutrition
Nuts
Oils and fats
Poultry and poultry products
Seafood
Spices and flavorings
Sugar
Vegetables
xx Agriculture
Nutrition

Footwear (02)
x Shoes
xx Clothing

Foreign aid (07)
xx Foreign relations

Foreign air carriers
see Air carriers

Foreign banking (02)
xx Banks, banking

Foreign claims (07, 12)
sa War claims
xx Claims
Foreign relations

Foreign currencies (02)
x Foreign exchange
xx Currency

Foreign exchange
see Currency
Foreign currencies

Foreign investments in U. S. (02)
xx Investments

Foreign officials (07, 13)
Foreign persons
see Aliens

Foreign relations (07)
sa *Specific countries*
Arms control
Citizenship and naturalization
Cultural exchange programs
Foreign aid
Foreign claims
Foreign Service
Foreign trade
Immigration
International boundaries
Passports and visas
Treaties

Foreign Service (07)
x Consular services
xx Foreign relations
Government employees

Foreign trade (02, 07)
sa Customs duties and inspection
Exports
Fairs and expositions
Imports
Maritime carriers
Trade adjustment assistance
Trade agreements
x International trade
xx Foreign relations

Foreign trade zones (02, 07)
Forests and forest products (01, 15)
sa National forests
x Lumber
Naval stores
Timber
Turpentine
Wood
xx Agriculture
Natural resources

Forfeitures
see Seizures and forfeitures

Forgery (12)
xx Crime

Foster care
see Adoption and foster care

Foundations (13)
Fraud (12)
xx Crime

Freedom of information (08)
sa Confidential business information
x Information
Records
xx Administrative practice and procedure

Freight (19)
sa Hazardous materials transportation
x Baggage
Cargo
xx Transportation

Freight forwarders (19)
x Shipping
xx Common carriers

Fringe benefits
see Employee benefit plans

Frozen foods (01)
xx Foods

Fruit juices (01)
xx Beverages

Fruits (01)
(The names of specific fruits, e.g. Apples, are not listed in this Thesaurus but may be used as indexing terms.)
sa *Specific fruits*
Citrus fruits
xx Agricultural commodities
Foods

Fuel
see Energy

Fuel additives (05)
x Additives
Gasoline additives
xx Petroleum

Fuel economy (05)
xx Energy conservation
Gasoline
Motor vehicles

Furs
Gambling (12)
sa Lotteries

Garnishment of wages
see Wages

Gas exploration
see Oil and gas exploration

Gas reserves
see Oil and gas reserves

Gas utilities
see Natural gas

Gases (15)
sa Helium
Natural gas

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FEDERAL REGISTER THESAURUS (REVISED)

Gasohol (05)
- xx Alcohol and alcoholic beverages
  - Gasoline

Gasoline (05)
- sa Fuel economy
  - Gasohol
- xx Petroleum

Gasoline additives
- see Fuel additives

Generally Recognized as Safe (GRAS) food ingredients
- see Food additives

Genetic diseases (09)

Geothermal energy (05)
- xx Energy

Gift taxes (02)
- xx Taxes

Gifts to Government
- see Government property

Glass and glass products (02)

Gold (02)
- xx Currency
  - Metals

Government buildings
- see Federal buildings and facilities

Government contracts (08)
- (Use for contracts for services in operating or researching specific government programs. Use Government procurement for contracting for supplies, equipment or related services.)
- sa Government procurement
- x Contracts
  - Defense contracts
  - National defense contracts
- xx Government procurement

Government employees (08, 11, 13)
- sa Conflict of interests
  - Foreign Service
  - Military personnel
  - Political activities (Government employees)
- x Civil service system
  - Federal employees
- xx Employment

Government in the Sunshine Act
- see Sunshine Act

Government procurement (08)
- (See note under Government contracts.)
- sa Government contracts
- x Defense acquisition regulations
  - Defense contracts
  - Federal procurement regulations
  - National defense contracts
  - Procurement
- xx Government contracts

Government property (08)
- sa Federal buildings and facilities
  - Government property management
  - Surplus Government property
- x Gifts to Government

Government property management (08)
- x Federal property management regulations
- xx Government property

Government publications (08)
- x Information
  - Publications

Government securities (02, 08)
- sa Bonds
- xx Securities

Grain sorghum (01)

Grains (01)
- (The names of specific grains, e.g. Wheat, are not listed in this Thesaurus but may be used as indexing terms.)
- sa *Specific grains*
  - Feed grains
- x Cereals (commodity)
- xx Agricultural commodities

Grant programs (08)
- (Use for programs involving financial aid without repayment by the Federal Government. Divide by the following categories to indicate broad subject area of grant: Agriculture, Business, Communications, Education, Energy, Environmental protection, Foreign relations, Health, Housing and community development, Indians, Labor, Law, National defense, Natural resources, Recreation, Science and technology, Social programs, Transportation, Veterans, e.g. Grant programs-agriculture)
- x Cooperative agreements
  - Federal aid programs
  - Subsidies
- xx Intergovernmental relations

Grants administration (08)

Grazing lands (15)
- x Land
- xx Public lands

Guaranteed loans
- see Loan programs

Guarantees
- see Warranties

Guns
- see Arms and munitions

Handicapped (09, 13)
- sa Blind
  - Disability benefits
  - Education of handicapped
  - Medicaid
  - Medicare
  - Public assistance programs
  - Supplemental Security Income (SSI)
  - Vocational rehabilitation
- x Architectural barriers
  - Deaf
  - Disabled
  - Discrimination against handicapped
  - Physically handicapped
- xx Health

Handicrafts
- see Arts and crafts

Hansen's disease
- see Leprosy (Hansen's disease)

Harbors (19)
- x Deepwater ports
  - Ports
  - Water transportation
  - Waterfront facilities
- xx Anchorage grounds
  - Waterways

Hatch Act
- see Political activities (Government employees)

Hazardous materials transportation (19)
- sa Pipeline safety
- x Dangerous cargo
- xx Explosives
  - Freight
  - Hazardous substances

Hazardous substances (09)
- sa Explosives
  - Flammable materials
  - Hazardous materials transportation
  - Hazardous waste
  - Poison prevention
  - Radioactive materials
- x Toxic substances
- xx Chemicals
  - Explosives
  - Safety

Hazardous waste (09)
- x Radioactive waste
- xx Hazardous substances
  - Waste treatment and disposal

Head Start Program
- see Education of disadvantaged

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Health (09)
sa *Specific diseases*
Dental health
Drug abuse
Drugs
Family planning
Handicapped
Health care
Health facilities
Health insurance
Health maintenance organizations (HMO)
Health professions
Health records
Health statistics
Maternal and child health
Medical and dental schools
Medical devices
Medical research
Mental health programs
Nutrition
Occupational safety and health
Public health
Quarantine
Radiation protection
Safety

Health care (09)
sa Emergency medical services
Health planning
Medicaid
Medicare
x Medical care
xx Health

Health facilities (09)
sa Hospitals
Nursing homes
x Medical facilities
xx Community facilities
Health
Nursing homes

Health insurance (02, 09)
sa Black lung benefits
Medicare
xx Health
Insurance

Health insurance for aged
see Medicare

Health maintenance organizations (HMO) (09)
(Prepaid group medical practice)
xx Health

Health planning (09)
xx Health care

Health professions (09, 13)
sa Veterinarians
x Doctors
Medical personnel
Physicians
xx Health

Health records (09)
x Medical records
Records
xx Health

Health statistics (09)
xx Health
Statistics

Hearing and appeal procedures
see Administrative practice and procedure

Heart diseases (09)
Helicopters
see Aircraft

Heliports
see Airports

Helium (15)
xx Gases

Hemophilia
see Blood diseases

Herbicides
see Pesticides and pests

Higher education
see Colleges and universities

Highway safety (09, 19)
xx Highways and roads
Safety

Highways and roads (19)
sa Bridges
Carpools
Highway safety
Motor carriers
Motor vehicle safety
Motor vehicles
Parking
x Roads
xx Transportation

Historic preservation (15)
sa Monuments and memorials
x Antiquities
Archaeology
National Register of Historic Places

Historical records
see Archives and records

Hobbies (16)
Hogs (01)
x Swine

Holding companies (02)
xx Business and industry

Holidays (08)
Home improvement (10)
xx Housing

Homesteads (15)
xx Public lands

Homeworkers (11, 13)
xx Labor

Hospitals (09)
xx Health facilities

Hostages
Hours of work
see Wages

Household appliances (02)
x Appliances

Household goods
see Moving of household goods

Housing (10)
sa Condominiums
Fair housing
Home improvement
Housing standards
Low and moderate income housing
Mobile homes
Mortgage insurance
Mortgages
New communities
Public housing
Relocation assistance

Housing assistance payments
see Mortgages
Rent subsidies

Housing standards (10)
xx Housing

Human research subjects
see Research

Humane treatment of animals
see Animal welfare

Hunting (16)
xx Recreation and recreation areas

Hydroelectric power
see Electric power

Immigration (07)
sa Aliens
Citizenship and naturalization
x Asylum
xx Aliens
Citizenship and naturalization
Foreign relations

Immunization (09)
xx Public health

Impacted areas programs
see Federally affected areas

Imports (02, 07)
sa Antidumping
Countervailing duties
Customs duties and inspection
Oil imports
Trade adjustment assistance
xx Customs duties and inspection
Foreign trade

Income taxes (02)
sa Tax treaties
xx Taxes

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Indemnity payments (08)
x Compensation
Federal aid programs

Indians (13)
sa Indians–arts and crafts
Indians–business and finance
Indians–claims
Indians–education
Indians–enrollment
Indians–judgment funds
Indians–lands
Indians–law
Indians–tribal government
x Alaska natives
American Indians
Eskimos
Native Americans

Indians–arts and crafts (04)
xx Arts and crafts
Indians

Indians–business and finance (02)
x Finance
xx Business and industry
Indians

Indians–claims (12)
xx Claims
Indians

Indians–education (04)
xx Education
Indians

Indians–enrollment (12)
xx Indians

Indians–judgment funds (12)
xx Indians

Indians–lands (15)
x Land
xx Indians

Indians–law (12)
xx Indians
Law

Indians–tribal government (12)
xx Indians

Industrial safety
see Occupational safety and health

Industry
see Business and industry

Infants and children (13)
sa Adoption and foster care
Aid to Families with Dependent Children
Child welfare
Youth
x Children
xx Youth

Information
see Archives and records
Classified information
Confidential business information
Freedom of information
Government publications
Privacy
Reporting and recordkeeping requirements
Sunshine Act

Inland waters
see Waterways

Insecticides
see Pesticides and pests

Insignia
see Seals and insignia

Insulation

Insurance (02)
sa Bank deposit insurance
Crime insurance
Crop insurance
Flood insurance
Health insurance
Insurance companies
Life insurance
Mortgage insurance
Pension insurance
Surety bonds
Unemployment compensation
War risk insurance
Workers' compensation

Insurance companies (02)
xx Insurance

Insured loans
see Loan programs

Intelligence
see Classified information

Interest equalization tax (02)
xx Taxes

Intergovernmental relations (08)
sa Grant programs
Revenue sharing
x Federal–State relations
State–Federal relations

Interlocking directorates
see Antitrust

Intermodal transportation (19)
xx Transportation

International agreements
see Treaties

International boundaries (07)
x Borders
xx Foreign relations

International expositions
see Fairs and expositions

International organizations (07)

International trade
see Foreign trade

Inventions and patents (17)
x Patents

Investigations (08, 12)

Investment advisers
see Securities

Investment companies (02)
xx Investments

Investments (02)
sa Brokers
Commodity futures
Foreign investments in U. S.
Investment companies
Securities
United States investments abroad
x Finance

Irrigation (01)
xx Agriculture
Water supply

Jewelry
see Watches and jewelry

Job Corps (11)

Job Training Partnership Act
see Manpower training programs

Jukeboxes

Juvenile delinquency (12)
x Delinquency
xx Crime
Youth

Kidney diseases (09)
x Renal diseases

Kites
see Aircraft

Labeling (02)
sa Food labeling
Packaging and containers
xx Business and industry
Consumer protection
Packaging and containers

Labor (11)
sa Child labor
Employee benefit plans
Employment
Equal employment opportunity
Homeworkers
Labor management relations
Manpower
Migrant labor
Occupational safety and health
Retirement
Unemployment compensation
Wages
xx Business and industry

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Labor management relations (11)
  sa Labor unions
  x Collective bargaining
    Employee management relations
  xx Labor

Labor unions (11)
  x Trade unions
    Unions
  xx Labor management relations

Laboratories (17)

Land
  see Grazing lands
    Indians–lands
    Public lands
    Rights–of–way

Land sales (10)
  sa Public lands–sale

Lasers (17)
  xx Scientific equipment

Law (12)
  sa Administrative practice and procedure
    Courts
    Indians–law
    Lawyers

Law enforcement (12)
  sa Drug traffic control
    Wiretapping and electronic surveillance

Law enforcement officers (12, 13)
  x Police

Lawyers (12, 13)
  sa Legal services
  x Attorneys
  xx Law

Lead poisoning (09)
  x Paint
  xx Poison prevention

Legal services (12)
  xx Lawyers

Leprosy (Hansen's disease) (09)
  x Hansen's disease

Libraries (04)
  xx Education

Life insurance (02)
  xx Insurance

Linseeds
  see Oilseeds

Liquors (01)
  x Distilled spirits
  xx Alcohol and alcoholic beverages

Livestock (01)
  (The names of specific animals, e.g. Cattle, are not listed in this Thesaurus but may be used as indexing terms.)
  sa *Specific animals*
    Meat and meat products
    Meat inspection
  x Domestic animals
  xx Animals

Loan programs (02, 08)
  (Use for Federal Government loan and loan guaranty programs. Divide by the following categories to indicate broad subject area of loan: Agriculture, Business, Communications, Education, Energy, Environmental protection, Foreign relations, Health, Housing and community development, Indians, Labor, Law, National defense, Natural resources, Recreation, Science and technology, Social programs, Transportation, Veterans, e.g. Loan programs–labor)
  x Federal aid programs
    Finance
    Guaranteed loans
    Insured loans

Lobbying (08)

Longshoremen (13, 19)

Lotteries (12)
  xx Gambling

Low and moderate income housing (10)
  sa Public housing
    Rent subsidies
  xx Housing
    Public housing

Lumber
  see Forests and forest products

Lung diseases (09)
  sa Black lung benefits
    Tuberculosis
  x Respiratory and pulmonary diseases

Magazines
  see Newspapers and magazines

Mail
  see Postal Service

Management official interlocks
  see Antitrust

Manpower (11)
  sa Manpower training programs
  xx Employment
    Labor

Manpower training programs (11)
  (Use for occupational or on–the–job training, distinguished from vocational education within a school curriculum)
  sa Vocational education
    Work Incentive Programs (WIN)
  x Apprenticeship programs
    Comprehensive Employment and Training Act
    Job Training Partnership Act
    Occupational training
    Training programs
    Unemployment
  xx Manpower
    Vocational education

Manufactured homes
  see Mobile homes

Margarine (01)
  x Oleomargarine
  xx Butter

Marine engineering
  see Vessels

Marine mammals (15)
  x Seals
    Whales

Marine pollution
  see Water pollution control

Marine resources (15)
  sa Fisheries
  x Ocean resources
  xx Natural resources

Marine safety (09, 19)
  sa Vessels
  x Boats and boating safety
    Water transportation
  xx Safety
    Vessels

Marital status discrimination (12)

Maritime carriers (19)
  (Organizations operating passenger or cargo carrying vessels)
  sa Cargo vessels
    Passenger vessels
    Seamen
    Vessels
  x Merchant marine
    Rates and fares
    Shipping
    Water carriers
    Water transportation
  xx Cargo vessels
    Common carriers
    Foreign trade
    Passenger vessels
    Vessels

Marketing agreements (01)
  sa Milk marketing orders
  xx Agricultural commodities

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- Marketing quotas (01)
  - xx Agricultural commodities
- Mass transportation (19)
  - xx Transportation
- Maternal and child health (09)
  - x Child health
  - Family health
  - xx Child welfare
  - Health
- Measurement standards (17)
  - sa Metric system
  - x Weights and measures
- Meat and meat products (01)
  - sa Meat inspection
  - Stockyards
  - x Beef
  - xx Foods
  - Livestock
- Meat inspection (01)
  - xx Food grades and standards
  - Livestock
  - Meat and meat products
  - Public health
- Medals
  - see Decorations, medals, awards
- Medicaid (09, 18)
  - sa Professional Standards Review Organizations (PSRO)
  - Public assistance programs
  - x Disabled
  - Medical assistance program
  - xx Aged
  - Blind
  - Handicapped
  - Health care
  - Public assistance programs
  - Social security
- Medical and dental schools (04, 09)
  - x Dental schools
  - Nursing schools
  - xx Colleges and universities
  - Health
- Medical assistance program
  - see Medicaid
- Medical care
  - see Health care
- Medical devices (09)
  - x Prosthetic devices
  - xx Health
  - Scientific equipment
- Medical facilities
  - see Health facilities
- Medical personnel
  - see Health professions
- Medical records
  - see Health records
- Medical research (09, 17)
  - xx Health
  - Research
- Medicare (09)
  - sa Professional Standards Review Organizations (PSRO)
  - x Disabled
  - Health insurance for aged
  - xx Aged
  - Handicapped
  - Health care
  - Health insurance
  - Social security
- Memorials
  - see Monuments and memorials
- Mental health programs (09)
  - xx Health
- Merchant marine
  - see Maritime carriers
  - Seamen
- Metals (15)
  - (The names of specific metals, e.g. Copper, are not listed in this Thesaurus but may be used as indexing terms.)
  - sa *Specific metals*
  - xx Mineral resources
- Metric system (17)
  - xx Measurement standards
- Micrographics (17)
- Migrant labor (01, 11, 13)
  - xx Agriculture
  - Labor
- Migratory birds
  - see Wildlife
- Military academies (04, 14)
  - xx Armed forces
  - Colleges and universities
- Military air transportation (14, 19)
  - xx Air transportation
  - National defense
- Military arms sales
  - see Arms and munitions
- Military installations
  - see Federal buildings and facilities
- Military law (12, 14)
  - x Uniform Code of Military Justice
  - xx Armed forces
- Military personnel (13, 14)
  - sa Armed forces reserves
  - xx Armed forces
  - Government employees
- Milk (01)
  - sa Milk marketing orders
- Milk marketing orders (01)
  - xx Marketing agreements
  - Milk
- Mine safety and health (09)
  - sa Black lung benefits
  - x Coal mines
  - xx Miners
  - Mines
  - Occupational safety and health
  - Safety
  - Surface mining
  - Underground mining
- Mineral resources (15)
  - sa Coal
  - Metals
  - Oil and gas reserves
  - Public lands-mineral resources
  - xx Natural resources
- Mineral royalties (15)
  - x Royalties
- Miners (13)
  - sa Mine safety and health
  - x Coal miners
  - xx Mines
- Mines (15)
  - sa Mine safety and health
  - Miners
  - Surface mining
  - Underground mining
  - x Coal mines
  - xx Reclamation
- Minimum wages (11)
  - xx Wages
- Minority businesses (02)
  - x Minority groups
  - xx Business and industry
  - Small businesses
  - Women
- Minority groups
  - see Civil rights
  - Minority businesses
- Mobile homes (10)
  - x Manufactured homes
  - xx Housing
- Mobile offshore drilling units
  - see Vessels
- Money
  - see Currency
- Monuments and memorials (15)
  - x Memorials
  - xx Historic preservation
- Mortgage insurance (02, 10)
  - xx Housing
  - Insurance
  - Mortgages

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Mortgages (02, 10)
sa Mortgage insurance
x Finance
Housing assistance payments
xx Credit
Housing

Motion pictures (03)
x Films
xx Communications

Motor carriers (19)
(Organizations operating passenger or cargo carrying motor vehicles)
sa Buses
x Rates and fares
Shipping
Trucks
xx Buses
Common carriers
Highways and roads
Motor vehicles

Motor vehicle pollution (06, 19)
xx Air pollution control
Motor vehicles

Motor vehicle safety (09, 19)
xx Highways and roads
Motor vehicles
Safety

Motor vehicles (19)
sa Buses
Carpools
Fuel economy
Motor carriers
Motor vehicle pollution
Motor vehicle safety
Traffic regulations
x Automobiles
Motorcycles
Trucks
xx Buses
Highways and roads

Motorcycles
see Motor vehicles

Moving of household goods (19)
x Household goods

Munitions
see Arms and munitions

Museums (04)
Music (04)
Narcotics
see Drug traffic control

National banks (02)
xx Banks, banking

National cemeteries
see Cemeteries

National defense (14)
sa Armed forces
Arms and munitions
Arms control
Civil defense
Classified information
Defense communications
Emergency powers
Military air transportation
Strategic and critical materials
x Defense

National defense contracts
see Government contracts
Government procurement

National forests (15)
xx Forests and forest products
Natural resources
Public lands
Recreation and recreation areas

National guard
see Armed forces reserves

National parks (15)
x Parks
xx Public lands
Recreation and recreation areas

National Register of Historic Places
see Historic preservation

National seashores
see Seashores

National security information
see Classified information

National trails system (16)
x Trails
xx Recreation and recreation areas

National wild and scenic rivers system (16)
xx Rivers

National Wildlife Refuge System
see Wildlife refuges

Nationality
see Citizenship and naturalization

Native Americans
see Indians

Natural gas (05)
sa Oil and gas exploration
Oil and gas reserves
Pipelines
x Gas utilities
Public utilities
Rates and fares
xx Energy
Gases
Pipelines
Utilities

Natural resources (15)
sa Coastal zone
Continental shelf
Energy
Environmental protection
Fish
Forests and forest products
Marine resources
Mineral resources
National forests
Public lands
Reclamation
Recreation and recreation areas
Soil conservation
Water resources
Wildlife
x Conservation
xx Environmental protection

Naturalization
see Citizenship and naturalization

Naval stores
see Forests and forest products

Navigable waters
see Waterways

Navigation (air) (19)
xx Air transportation

Navigation (water) (19)
x Boats and boating safety
Water transportation
xx Vessels

New communities (10)
x Planned communities
xx Housing

News media (03)
sa Newspapers and magazines
Radio
Television
xx Communications

Newspapers and magazines (03)
x Magazines
xx News media

Noise control (06, 19)
xx Environmental protection
Transportation

Nondiscrimination
see Civil rights

Nonprofit organizations (13)
Nuclear energy (05)
sa Nuclear materials
Nuclear power plants and reactors
x Atomic energy
xx Energy

Nuclear materials (05)
xx Nuclear energy
Radioactive materials

Nuclear power plants and reactors (05)
xx Nuclear energy

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Nuclear safety
see Radiation protection

Nuclear vessels (19)
xx Vessels

Nursery stock (01)
sa Plants (agriculture)

Nursing homes (09)
sa Health facilities
xx Health facilities

Nursing schools
see Medical and dental schools

Nutrition (09)
sa Food assistance programs
Foods
xx Foods
Health

Nuts (01)
xx Agricultural commodities
Foods

Occupational safety and health (09, 11)
sa Mine safety and health
Workers' compensation
x Industrial safety
xx Health
Labor
Safety

Occupational training
see Manpower training programs
Vocational education

Ocean dumping
see Water pollution control

Ocean resources
see Marine resources

Oceanographic research vessels (19)
xx Vessels

Off-road vehicles
see Traffic regulations

Offshore structures
see Continental shelf

Oil
see Oils and fats
Petroleum

Oil and gas exploration (05)
x Gas exploration
xx Natural gas
Petroleum

Oil and gas reserves (05, 15)
x Gas reserves
xx Mineral resources
Natural gas
Petroleum

Oil imports (02, 05, 07)
xx Imports
Petroleum

Oil pollution (06)
xx Petroleum
Vessels
Water pollution control

Oils and fats (01)
sa Oilseeds
x Fats and oils
Oil
xx Foods

Oilseeds (01)
sa Cottonseeds
x Flaxseeds
Linseeds
Tung nuts
xx Agricultural commodities
Oils and fats

Old-age, Survivors and Disability Insurance (11, 18)
Oleomargarine
see Margarine

Ophthalmic goods and services
Organization and functions (Government agencies) (08)
sa Authority delegations (Government agencies)
xx Authority delegations (Government agencies)

Outer continental shelf
see Continental shelf

Over-the-counter drugs (09)
xx Drugs

Overseas private investment
see United States investments abroad

Overtime pay
see Wages

Packaging and containers (02)
sa Food packaging
Labeling
x Barrels
Containers
xx Business and industry
Labeling

Paint
see Lead poisoning

Paperwork requirements
see Reporting and recordkeeping requirements

Parachutes
see Aircraft

Pardon
see Clemency

Parking (19)
xx Highways and roads

Parks
see National parks

Parole
see Probation and parole

Passenger vessels (19)
sa Maritime carriers
xx Maritime carriers
Vessels

Passports and visas (07, 19)
x Visas
xx Foreign relations
Travel

Patents
see Inventions and patents

Pay
see Wages

Penalties (12)
sa Seizures and forfeitures
x Fines and penalties

Pension insurance (11)
xx Insurance
Pensions

Pensions (11)
sa Pension insurance
Railroad retirement
Social security
x Annuities
Employee Retirement Income Security Act
xx Employee benefit plans
Retirement

Pesticides and pests (01, 06)
sa Plant diseases and pests
x Herbicides
Insecticides
Rodenticides
xx Agriculture
Chemicals
Environmental protection

Petroleum (05)
sa Fuel additives
Gasoline
Oil and gas exploration
Oil and gas reserves
Oil imports
Oil pollution
Petroleum allocation
Petroleum price regulations
Pipelines
x Crude oil
Oil
xx Energy

Petroleum allocation (05)
xx Petroleum

Petroleum price regulations (02, 05)
xx Petroleum
Price controls

Pets (01)
xx Animals

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Physically handicapped
see Handicapped

Physicians
see Health professions

Pilots
see Airmen

Pipeline safety (09, 19)
xx Hazardous materials transportation
Pipelines
Safety

Pipelines (05, 19)
sa Natural gas
Pipeline safety
xx Energy
Natural gas
Petroleum
Transportation

Planned communities
see New communities

Plant diseases and pests (01)
xx Pesticides and pests
Plants (agriculture)

Plants (agriculture) (01)
sa Plant diseases and pests
Seeds
xx Nursery stock

Plastics materials and synthetics (02)
Pneumoconiosis
see Black lung benefits

Poison prevention (09)
sa Lead poisoning
x Toxic substances
xx Hazardous substances
Safety

Police
see Law enforcement officers

Political activities (Government employees) (08)
x Hatch Act
xx Conflict of interests
Elections
Government employees

Political affiliation discrimination (12)
Political candidates (08)
sa Campaign funds
xx Elections

Political committees and parties (08)
xx Elections

Pollution
see Environmental protection

Population census
see Census data

Population control
see Family planning

Ports
see Harbors

Postal Service (03)
x Mail
Rates and fares

Posters
see Signs and symbols

Poultry and poultry products (01)
xx Foods

Poverty
see Community action programs
Food assistance programs
Public assistance programs

Power resources
see Energy

Practice and procedure
see Administrative practice and procedure

Prescription drugs (09)
xx Drugs

Presidential documents (08)
sa Executive orders
Proclamations

Presidential elections
see Elections

Price controls (02)
sa Petroleum price regulations
x Economics

Price support programs (01)
x Federal aid programs
xx Agricultural commodities

Prisoners (12, 13)
Prisoners of war (13, 14)
Prisons (12)
sa Federal Prison Industries
Probation and parole

Privacy (08, 12)
sa Confidential business information
x Information
Records
xx Administrative practice and procedure

Private schools (04)
xx Schools

Probation and parole (12)
x Parole
xx Prisons

Proclamations (08)
xx Presidential documents

Procurement
see Government procurement

Professional Standards Review Organizations (PSRO) (09)
xx Medicaid
Medicare

Prosthetic devices
see Medical devices

Public assistance programs (18)
(Cash assistance programs under the Social Security Act)
sa Aid to Families with Dependent Children
Child welfare
Medicaid
Supplemental Security Income (SSI)
x Disabled
Poverty
Welfare programs
xx Aged
Aid to Families with Dependent Children
Blind
Handicapped
Medicaid
Social security

Public buildings
see Federal buildings and facilities

Public health (09)
sa Immunization
Meat inspection
Quarantine
Waste treatment and disposal
x Sanitation
xx Health

Public housing (10)
sa Low and moderate income housing
Rent subsidies
xx Housing
Low and moderate income housing

Public lands (15)
sa Grazing lands
Homesteads
National forests
National parks
Public lands–classification
Public lands–grants
Public lands–mineral resources
Public lands–rights-of-way
Public lands–sale
Public lands–withdrawal
Reclamation
x Land
xx Natural resources

Public lands–classification (15)
xx Public lands

Public lands–grants (15)
xx Public lands

Public lands–mineral resources (15)
xx Mineral resources
Public lands

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Public lands–rights–of–way (15)
  xx Public lands
  Rights–of–way

Public lands–sale (15)
  xx Land sales
  Public lands

Public lands–withdrawal (15)
  xx Public lands

Public meetings
  see Sunshine Act

Public utilities
  see Electric utilities
  Natural gas
  Utilities
  Water supply

Public works
  see Community facilities

Publications
  see Government publications

Quarantine (09)
  xx Health
  Public health

Radiation protection (09)
  sa Radioactive materials
  x Nuclear safety
  xx Health
  Radioactive materials
  Safety

Radio (03)
  x Amateur radio service
  Broadcasting
  Citizens band radio service
  xx News media
  Telecommunications

Radioactive materials (09)
  sa Nuclear materials
  Radiation protection
  xx Hazardous substances
  Radiation protection

Radioactive waste
  see Hazardous waste

Railroad employees (13, 19)
  sa Railroad retirement
  Railroad unemployment insurance
  xx Railroads

Railroad retirement (11)
  xx Disability benefits
  Pensions
  Railroad employees
  Railroads
  Retirement

Railroad safety (09, 19)
  xx Railroads
  Safety

Railroad unemployment insurance (11)
  xx Railroad employees
  Railroads
  Unemployment compensation

Railroads (19)
  sa Railroad employees
  Railroad retirement
  Railroad safety
  Railroad unemployment insurance
  x Rates and fares
  Shipping
  xx Common carriers
  Transportation

Range management (01)
  xx Agriculture

Rates and fares
  see Air rates and fares
  Communications common carriers
  Electric power rates
  Maritime carriers
  Motor carriers
  Natural gas
  Postal Service
  Railroads

Real property acquisition (10)

Reclamation (15)
  sa Mines
  Surface mining
  xx Environmental protection
  Natural resources
  Public lands

Recordings (03)
  xx Communications

Records
  see Archives and records
  Freedom of information
  Health records
  Privacy
  Reporting and recordkeeping requirements

Recreation and recreation areas (16)
  sa Fishing
  Hunting
  National forests
  National parks
  National trails system
  Rivers
  Seashores
  Wilderness areas
  xx Natural resources

Recreational fishing
  see Fishing

Recycling (06)
  xx Waste treatment and disposal

Refugees (07, 13)
  sa Aliens
  xx Aliens

Religious discrimination (12)
  xx Civil rights

Relocation assistance (10)
  xx Business and industry
  Housing

Renal diseases
  see Kidney diseases

Rent subsidies (10)
  x Housing assistance payments
  Subsidies
  xx Low and moderate income housing
  Public housing

Repatriation
  see Citizenship and naturalization

Reporting and recordkeeping requirements (08)
  x Information
  Paperwork requirements
  Records

Research (17)
  sa Agricultural research
  Educational research
  Medical research
  x Human research subjects

Reserve forces
  see Armed forces reserves

Reservoirs (15)
  xx Flood control
  Water supply

Respiratory and pulmonary diseases
  see Lung diseases

Retirement (11)
  sa Pensions
  Railroad retirement
  Social security
  xx Labor

Revenue sharing (02, 08)
  x Finance
  xx Intergovernmental relations

Rights–of–way (12)
  sa Public lands–rights–of–way
  x Land

Rivers (16, 19)
  sa National wild and scenic rivers system
  xx Recreation and recreation areas
  Waterways

Roads
  see Highways and roads

Rockets
  see Aircraft

Rodenticides
  see Pesticides and pests

Rotorcraft
  see Aircraft

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Royalties
see Copyright
Mineral royalties

Rubber and rubber products (02)
sa Tires

Rugs
see Carpets and rugs

Rural areas (01)
xx Agriculture

Safety (09)
sa Aviation safety
Consumer protection
Fire prevention
Hazardous substances
Highway safety
Marine safety
Mine safety and health
Motor vehicle safety
Occupational safety and health
Pipeline safety
Poison prevention
Radiation protection
Railroad safety
x Accidents
xx Health

Salaries
see Wages

Sanitation
see Public health
Waste treatment and disposal

Satellites (17)
sa Space transportation and exploration
xx Telecommunications

Savings and loan associations (02)
xx Banks, banking

Savings bonds
see Bonds

Scholarships and fellowships (04)
x Fellowships
xx Student aid

School breakfast and lunch programs (01, 04, 18)
xx Education
Food assistance programs

School construction (04)
xx Education
Schools

School integration
see Equal educational opportunity

Schools (04)
sa Colleges and universities
Educational facilities
Private schools
School construction
xx Education

Science and technology (17)
x Technology

Scientific equipment (17)
sa Lasers
Medical devices

Scientists (13, 17)
Seafood (01)
(Use for documents on fish as food. Use Fish for documents on conservation, etc., of fish as marine life)
sa Fish
Fisheries
xx Fish
Foods

Seals
see Marine mammals

Seals and insignia (08)
x Insignia
Symbols
xx Signs and symbols

Seamen (13, 19)
x Merchant marine
xx Maritime carriers

Seaplanes
see Aircraft

Search warrants (12)
Seashores (16)
sa Coastal zone
x Beaches
National seashores
xx Coastal zones
Recreation and recreation areas

Secondary education
see Elementary and secondary education

Securities (02)
sa Bonds
Government securities
x Investment advisers
Stocks
xx Investments

Security information
see Classified information

Security measures (08)
sa Classified information

Seeds (01)
xx Plants (agriculture)

Segregation in education
see Equal educational opportunity

Seizures and forfeitures (12)
x Forfeitures
xx Penalties

Selective service system (14)
x Draft
xx Armed forces

Senior citizens
see Aged

Serums
see Biologics

Sewage disposal (06)
xx Waste treatment and disposal

Sex discrimination (12)
xx Civil rights
Women

Shipping
see Air carriers
Freight forwarders
Maritime carriers
Motor carriers
Railroads

Ships
see Vessels

Shoes
see Footwear

Signs and symbols (03)
sa Seals and insignia
Trademarks
x Posters
Symbols

Silver (02)
xx Currency
Metals

Sirup
see Sugar

Slum clearance
see Urban renewal

Small businesses (02)
sa Minority businesses
xx Business and industry

Smoking (09)
xx Cigars and cigarettes

Social security (11, 18)
sa Aid to Families with Dependent Children
Child welfare
Medicaid
Medicare
Public assistance programs
Supplemental Security Income (SSI)
Unemployment compensation
xx Pensions
Retirement

Soil conservation (01,15)
xx Natural resources

Solar energy (05)
xx Energy

Solid waste disposal
see Waste treatment and disposal

See refers to authorized terms; x refers from terms not used; sa refers to more specific or related terms; xx refers from broader or related terms
Number in parenthesis refer to subject category listings following alphabetical listing of terms

Space transportation and exploration (17, 19)
xx Satellites
Transportation

Spices and flavorings (01)
x Flavorings
xx Foods

Sport fishing
see Fishing

Stamp taxes
see Excise taxes

State–Federal relations
see Intergovernmental relations

Statistics (08)
sa Census data
Economic statistics
Health statistics

Sterilization
see Family planning

Stockpiling
see Strategic and critical materials

Stocks
see Securities

Stockyards (01)
xx Meat and meat products

Strategic and critical materials (14)
x Stockpiling
xx National defense

Strip mining
see Surface mining

Student aid (04)
sa Scholarships and fellowships
xx Colleges and universities
Education

Students (04, 13)
xx Education

Subsidies
see Grant programs
Rent subsidies

Sugar (01)
x Sirup
Syrup
xx Foods

Sunshine Act (08)
x Government in the Sunshine Act
Information
Public meetings
xx Administrative practice and procedure

Supplemental Security Income (SSI) (18)
(Assistance to aged, blind and disabled)
x Disabled
xx Aged
Blind
Handicapped
Public assistance programs
Social Security

Surety bonds (02)
x Bonding
xx Insurance

Surface mining (15)
sa Mine safety and health
x Coal mines
Strip mining
xx Mines
Reclamation

Surplus agricultural commodities (01)
xx Agricultural commodities

Surplus Government property (08)
xx Government property

Swine
see Hogs

Symbols
see Seals and insignia
Signs and symbols

Syrup
see Sugar

Tank vessels
see Cargo vessels

Tariffs
see Customs duties and inspection

Tax treaties (02, 07)
xx Income taxes
Taxes
Treaties

Taxes (02)
sa Customs duties and inspection
Employment taxes
Estate taxes
Excise taxes
Gift taxes
Income taxes
Interest equalization tax
Tax treaties
xx Business and industry

Tea (01)
xx Beverages

Teachers (04, 13)
xx Education

Technical assistance (08)
x Federal aid programs

Technical education
see Vocational education

Technology
see Science and technology

Telecommunications (03)
sa Radio
Satellites
Telegraph
Telephone
Television
xx Communications

Telegraph (03)
xx Telecommunications

Telephone (03)
xx Telecommunications

Television (03)
sa Cable television
x Broadcasting
xx News media
Telecommunications

Textiles (02)
x Fabrics

Timber
see Forests and forest products

Time (08)
Tires
xx Rubber and rubber products

Tobacco (01)
sa Cigars and cigarettes

Toiletries
see Cosmetics

Tort claims
see Claims

Tourist trade
see Travel

Toxic substances
see Hazardous substances
Poison prevention

Toxins
see Biologics

Toys
Trade adjustment assistance (02, 07)
(Aid to domestic industries or workers injured by competition from imported products)
x Adjustment assistance
xx Business and industry
Foreign trade
Imports

Trade agreements (02, 07)
xx Foreign trade
Treaties

Trade fairs
see Fairs and expositions

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Number in parenthesis refer to subject category listings following alphabetical listing of terms

Trade names (02)
xx Business and industry

Trade practices (02)
xx Business and industry
Consumer protection

Trade unions
see Labor unions

Trademarks (02)
xx Business and industry
Signs and symbols

Traffic regulations (19)
x Off-road vehicles
xx Motor vehicles

Trails
see National trails system

Training programs
see Manpower training programs

Transportation (19)
sa Air transportation
Bridges
Common carriers
Freight
Highways and roads
Intermodal transportation
Mass transportation
Noise control
Pipelines
Railroads
Space transportation and exploration
Vessels

Travel (19)
sa Passports and visas
Travel and transportation expenses
Travel restrictions
x Tourist trade

Travel and transportation expenses (19)
xx Travel

Travel restrictions (19)
xx Travel

Treaties (07)
sa Tax treaties
Trade agreements
x International agreements
xx Foreign relations

Trucks
see Motor carriers
Motor vehicles

Trusts and trustees (02)
x Finance
xx Banks, banking

Truth in lending (02)
xx Consumer protection
Credit

Tuberculosis (09)
xx Lung diseases

Tung nuts
see Oilseeds

Turpentine
see Forests and forest products

Underground mining (15)
sa Mine safety and health
x Coal mines
xx Mines

Unemployment
see Community development
Manpower training programs
Unemployment compensation

Unemployment compensation (11)
sa Railroad unemployment insurance
x Compensation
Unemployment
xx Insurance
Labor
Social security

Uniform Code of Military Justice
see Military law

Uniform System of Accounts (02, 08)
(Use for uniform financial reporting requirements for common carriers.)
xx Accounting

Unions
see Labor unions

United States investments abroad (02)
x Overseas private investment
xx Investments

Universities
see Colleges and universities

Upward Bound Program
see Education of disadvantaged

Uranium
Urban renewal (10)
sa Community development
x Slum clearance
xx Community development

Utilities (02, 05, 15)
sa Electric utilities
Natural gas
Water supply
x Public utilities

Vaccines
see Biologics

Vanpools
see Carpools

Vegetable juices (01)
xx Beverages

Vegetables (01)
(The names of specific vegetables, e.g. Potatoes, are not listed in this Thesaurus but may be used as indexing terms.)
sa *Specific vegetables*
xx Agricultural commodities
Foods

Venereal diseases (09)
Vessels (19)
sa Anchorage grounds
Cargo vessels
Fishing vessels
Marine safety
Maritime carriers
Navigation (water)
Nuclear vessels
Oceanographic research vessels
Oil pollution
Passenger vessels
x Marine engineering
Mobile offshore drilling units
Ships
Water transportation
xx Marine safety
Maritime carriers
Transportation

Veterans (13, 14)
Veterinarians (01, 13)
xx Health professions

Viruses
see Biologics

Visas
see Passports and visas

Vocational education (04)
(Use for vocational instruction within a school curriculum. Distinguish from manpower training programs for on-the-job training)
sa Manpower training programs
x Occupational training
Technical education
xx Education
Manpower training programs

Vocational rehabilitation (18)
(Training of the handicapped for employment)
xx Handicapped

Voluntary standards (02)
Volunteers (13)
Voting rights (08, 12)
xx Civil rights
Elections

See refers to authorized terms; x refers from terms not used; sa refers to more specific or related terms; xx refers from broader or related terms
Number in parenthesis refer to subject category listings following alphabetical listing of terms

Wages (11)
sa Employee benefit plans
Minimum wages
x Compensation
Garnishment of wages
Hours of work
Overtime pay
Pay
Salaries
xx Labor

War claims (07, 12)
xx Claims
Foreign claims

War risk insurance (02)
xx Insurance

Warehouses (02)
Warranties (02)
x Guarantees
xx Business and industry

Waste treatment and disposal (06)
sa Hazardous waste
Recycling
Sewage disposal
x Sanitation
Solid waste disposal
xx Environmental protection
Public health
Water pollution control

Watches and jewelry
x Jewelry

Water bank program (15)
xx Water resources

Water carriers
see Maritime carriers

Water pollution control (06)
sa Oil pollution
Waste treatment and disposal
x Marine pollution
Ocean dumping
xx Environmental protection

Water resources (15)
sa Water bank program
Water supply
Watersheds
xx Natural resources

Water supply (15)
sa Dams
Irrigation
Reservoirs
x Drinking water
Public utilities
xx Utilities
Water resources

Water transportation
see Anchorage grounds
Harbors
Marine safety
Maritime carriers
Navigation (water)
Vessels
Waterways

Waterfowl
see Wildlife

Waterfront facilities
see Harbors

Watersheds (15)
xx Water resources

Waterways (19)
sa Bridges
Harbors
Rivers
x Inland waters
Navigable waters
Water transportation

Weapons
see Arms and munitions

Weather (17)
Weights and measures
see Measurement standards

Welfare programs
see Public assistance programs

Wetlands
see Coastal zone
Flood plains

Whales
see Marine mammals

Wilderness areas (16)
xx Recreation and recreation areas

Wildlife (15)
sa Endangered and threatened wildlife
Wildlife refuges
x Birds
Migratory birds
Waterfowl
xx Animals
Natural resources

Wildlife refuges (15)
x National Wildlife Refuge System
xx Wildlife

Wine (01)
xx Alcohol and alcoholic beverages

Wiretapping and electronic surveillance (12)
x Eavesdropping
Electronic surveillance
xx Law enforcement

Women (13)
sa Minority businesses
Sex discrimination

Wood
see Forests and forest products

Work Incentive Programs (WIN) (11)
xx Aid to Families with Dependent Children
Manpower training programs

Workers' compensation (11)
x Compensation
xx Disability benefits
Insurance
Occupational safety and health

X-rays (17)
Youth (13)
sa Infants and children
Juvenile delinquency
xx Infants and children

Zoning (10)

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Number in parenthesis refer to subject category listings following alphabetical listing of terms

01

AGRICULTURE AND FOOD

Acreage allotments
Agricultural commodities
Agricultural research
Agriculture
Alcohol and alcoholic beverages
Animal biologics
Animal diseases
Animal drugs
Animal feeds
Animal foods
Animal welfare
Animals
Bakery products
Beer
Bees
Beverages
Butter
Cacao products
Candy
Cereals (food)
Chemicals
Cigars and cigarettes
Citrus fruits
Coffee
Color additives
Commodity futures
Cottonseeds
Crop insurance
Dairy products
Dietary foods
Feed grains
Fertilizers
Food additives
Food assistance programs
Food grades and standards
Food labeling
Food packaging
Food stamps
Foods
Forests and forest products
Frozen foods
Fruit juices
Fruits
Grain sorghum
Grains
Hogs
Irrigation
Liquors
Livestock
Margarine
Marketing agreements
Marketing quotas
Meat and meat products
Meat inspection
Migrant labor
Milk
Milk marketing orders
Nursery stock
Nuts
Oils and fats
Oilseeds
Pesticides and pests
Pets
Plant diseases and pests
Plants (agriculture)
Poultry and poultry products
Price support programs
Range management
Rural areas
School breakfast and lunch programs
Seafood
Seeds
Soil conservation
Spices and flavorings
Stockyards
Sugar
Surplus agricultural commodities
Tea
Tobacco
Vegetable juices
Vegetables
Veterinarians
Wine

02

COMMERCE

Accountants
Accounting
Advertising
Antidumping
Antitrust
Bank deposit insurance
Bankruptcy
Banks, banking
Bonds
Brokers
Business and industry
Clothing
Commodity futures
Common carriers
Communications common carriers
Concessions
Confidential business information
Consumer protection
Countervailing duties
Credit
Credit unions
Crime insurance
Crop insurance
Currency
Customs duties and inspection
Economic statistics
Electronic funds transfers
Employment taxes
Estate taxes
Estates
Excise taxes
Exports
Fairs and expositions
Federal home loan banks
Federal Reserve System
Flood insurance
Footwear
Foreign banking
Foreign currencies
Foreign investments in U. S.
Foreign trade
Foreign trade zones
Gift taxes
Glass and glass products
Gold
Government securities
Health insurance
Holding companies
Household appliances
Imports
Income taxes
Indians–business and finance
Insurance
Insurance companies
Interest equalization tax
Investment companies
Investments
Labeling
Life insurance
Loan programs
Minority businesses
Mortgage insurance
Mortgages
National banks
Oil imports
Packaging and containers
Petroleum price regulations
Plastics materials and synthetics
Price controls
Revenue sharing
Rubber and rubber products
Savings and loan associations
Securities
Silver
Small businesses
Surety bonds
Tax treaties
Taxes
Textiles
Trade adjustment assistance
Trade agreements
Trade names
Trade practices
Trademarks
Trusts and trustees
Truth in lending
Uniform System of Accounts
United States investments abroad
Utilities
Voluntary standards
War risk insurance
Warehouses
Warranties

03

COMMUNICATIONS

Cable television
Communications
Communications common carriers
Communications equipment
Defense communications
Motion pictures
News media
Newspapers and magazines
Postal Service
Radio
Recordings
Signs and symbols
Telecommunications
Telegraph
Telephone
Television

04

EDUCATION

Adult education
Art
Arts and crafts
Bilingual education
Colleges and universities
Cultural exchange programs
Education
Education of disadvantaged
Education of handicapped
Educational facilities
Educational research
Educational study programs
Elementary and secondary education
Equal educational opportunity

Indians–arts and crafts
Indians–education
Libraries
Medical and dental schools
Military academies
Museums
Music
Private schools
Scholarships and fellowships
School breakfast and lunch programs
School construction
Schools
Student aid
Students
Teachers
Vocational education

05

ENERGY

Coal
Coal conversion program
Electric power
Electric power plants
Electric power rates
Electric utilities
Energy
Energy conservation
Fuel additives
Fuel economy
Gasohol
Gasoline
Geothermal energy
Natural gas
Nuclear energy
Nuclear materials
Nuclear power plants and reactors
Oil and gas exploration
Oil and gas reserves
Oil imports
Petroleum
Petroleum allocation
Petroleum price regulations
Pipelines
Solar energy
Utilities

06

ENVIRONMENTAL PROTECTION

Air pollution control
Environmental impact statements
Environmental protection
Motor vehicle pollution
Noise control
Oil pollution
Pesticides and pests
Recycling
Sewage disposal
Waste treatment and disposal
Water pollution control

07

FOREIGN RELATIONS

Alien property
Aliens
Antidumping
Arms control
Boycotts
Citizenship and naturalization
Communist countries
Countervailing duties
Cultural exchange programs
Customs duties and inspection
Exports
Fairs and expositions
Foreign aid
Foreign claims
Foreign officials
Foreign relations
Foreign Service
Foreign trade
Foreign trade zones
Immigration
Imports
International boundaries
International organizations
Oil imports
Passports and visas
Refugees
Tax treaties
Trade adjustment assistance
Trade agreements
Treaties
War claims

08

GOVERNMENT

Accounting
Administrative practice and procedure
Advisory committees
Archives and records
Authority delegations (Government agencies)
Campaign funds
Census data
Conflict of interests
Decorations, medals, awards
Disaster assistance
Elections
Emergency powers
Equal access to justice
Executive orders
Federal buildings and facilities
Federally affected areas
Flags
Freedom of information
Government contracts
Government employees
Government procurement
Government property
Government property management
Government publications
Government securities
Grant programs
Grants administration
Holidays
Indemnity payments
Intergovernmental relations
Investigations
Loan programs
Lobbying
Organization and functions (Government agencies)
Political activities (Government employees)
Political candidates
Political committees and parties
Presidential documents
Privacy
Proclamations
Reporting and recordkeeping requirements
Revenue sharing
Seals and insignia
Security measures
Statistics
Sunshine Act
Surplus government property
Technical assistance
Time
Uniform System of Accounts
Voting rights

09

HEALTH AND SAFETY

Alcoholism
Animal biologics
Animal diseases
Animal drugs
Antibiotics
Aviation safety
Biologics
Black lung benefits
Blind
Blood
Blood diseases
Cancer
Chemicals
Color additives
Communicable diseases
Cosmetics
Dental health
Drug abuse
Drugs
Emergency medical services
Explosives
Family planning
Fire prevention
Flammable materials
Genetic diseases
Handicapped
Hazardous substances
Hazardous waste
Health
Health care
Health facilities
Health insurance
Health maintenance organizations (HMO)
Health planning
Health professions
Health records
Health statistics
Heart diseases
Highway safety
Hospitals
Immunization
Kidney diseases
Lead poisoning
Leprosy (Hansen's disease)
Lung diseases
Marine safety
Maternal and child health
Medicaid
Medical and dental schools
Medical devices
Medical research
Medicare
Mental health programs
Mine safety and health
Motor vehicle safety
Nursing homes
Nutrition
Occupational safety and health
Over–the–counter drugs
Pipeline safety
Poison prevention
Prescription drugs

Professional Standards Review Organizations (PSRO)
Public health
Quarantine
Radiation protection
Radioactive materials
Railroad safety
Safety
Smoking
Tuberculosis
Venereal diseases
Veterinarians

10

HOUSING AND COMMUNITY DEVELOPMENT

Buildings
Community development
Community development block grants
Community facilities
Condominiums
Fair housing
Home improvement
Housing
Housing standards
Land sales
Low and moderate income housing
Mobile homes
Mortgage insurance
Mortgages
New communities
Public housing
Real property acquisition
Relocation assistance
Rent subsidies
Urban renewal
Zoning

11

LABOR

Child labor
Disability benefits
Employee benefit plans
Employment
Equal employment opportunity
Government employees
Homeworkers
Job Corps
Labor
Labor management relations
Labor unions
Manpower
Manpower training programs
Migrant labor
Minimum wages
Occupational safety and health
Old-age, Survivors and Disability Insurance
Pension insurance
Pensions
Railroad retirement
Railroad unemployment insurance
Retirement
Social security
Unemployment compensation
Wages
Work Incentive Programs (WIN)
Workers' compensation

12

LAW

Alimony
Civil disorders
Civil rights
Claims
Clemency
Copyright
Counterfeiting
Courts
Crime
Drug traffic control
Equal educational opportunity
Equal employment opportunity
Fair housing
Federal Prison Industries
Foreign claims
Forgery
Fraud
Gambling
Indians–claims
Indians–enrollment
Indians–judgment funds
Indians–law
Indians–tribal government
Investigations
Juvenile delinquency
Law
Law enforcement
Law enforcement officers
Lawyers
Legal services
Lotteries
Marital status discrimination
Military law
Penalties
Political affiliation discrimination
Prisoners
Prisons
Privacy
Probation and parole
Religious discrimination
Rights-of-way
Search warrants
Seizures and forfeitures
Sex discrimination
Voting rights
War claims
Wiretapping and electronic surveillance

13

NAMED GROUPS

Accountants
Aged
Airmen
Aliens
Architects
Blind
Brokers
Chaplains
Child labor
Conscientious objectors
Consultants
Engineers
Firefighters
Foreign officials
Foundations
Government employees
Handicapped
Health professions
Homeworkers
Indians
Infants and children
Law enforcement officers
Lawyers
Longshoremen
Migrant labor
Military personnel
Miners
Nonprofit organizations
Prisoners
Prisoners of war
Railroad employees
Refugees
Scientists
Seamen
Students
Teachers
Veterans
Veterinarians
Volunteers
Women
Youth

14

NATIONAL DEFENSE

Armed forces
Armed forces reserves
Arms and munitions
Arms control
Civil defense
Classified information
Conscientious objectors
Defense communications
Emergency powers
Fallout shelters
Military academies
Military air transportation
Military law
Military personnel
National defense
Prisoners of war
Selective service system
Strategic and critical materials
Veterans

15

NATURAL RESOURCES

Coastal zone
Continental shelf
Dams
Endangered and threatened wildlife
Fish
Fisheries
Flood control
Flood plains
Forests and forest products
Gases
Grazing lands
Helium
Historic preservation
Homesteads
Indians–lands
Marine mammals
Marine resources
Metals
Mineral resources
Mineral royalties
Mines
Monuments and memorials
National forests

National parks
Natural resources
Oil and gas reserves
Public lands
Public lands–classification
Public lands–grants
Public lands–mineral resources
Public lands–rights-of-way
Public lands–sale
Public lands–withdrawal
Reclamation
Reservoirs
Soil conservation
Surface mining
Underground mining
Utilities
Water bank program
Water resources
Water supply
Watersheds
Wildlife
Wildlife refuges

16

RECREATION

Bicycles
Fishing
Hobbies
Hunting
National trails system
National wild and scenic rivers system
Recreation and recreation areas
Rivers
Seashores
Wilderness areas

17

SCIENCE AND TECHNOLOGY

Agricultural research
Computer technology
Educational research
Electronic products
Inventions and patents
Laboratories
Lasers
Measurement standards
Medical research
Metric system
Micrographics
Research
Satellites
Science and technology
Scientific equipment
Scientists
Space transportation and exploration
Weather
X-rays

18

SOCIAL PROGRAMS

Adoption and foster care
Aid to Families with Dependent Children
Child support
Child welfare
Community action programs
Day care
Family planning
Food assistance programs
Food stamps
Medicaid
Old-age, Survivors and Disability Insurance
Public assistance programs
School breakfast and lunch programs
Social security
Supplemental Security Income (SSI)
Vocational rehabilitation

19

TRANSPORTATION

Air carriers
Air rates and fares
Air taxis
Air traffic control
Air transportation
Aircraft
Airmen
Airports
Airspace
Anchorage grounds
Aviation safety
Bicycles
Bridges
Buses
Cargo vessels
Carpools
Charter flights
Common carriers
Fishing vessels
Freight
Freight forwarders
Harbors
Hazardous materials transportation
Highway safety
Highways and roads
Intermodal transportation
Longshoremen
Marine safety
Maritime carriers
Mass transportation
Military air transportation
Motor carriers
Motor vehicle pollution
Motor vehicle safety
Motor vehicles
Moving of household goods
Navigation (air)
Navigation (water)
Noise control
Nuclear vessels
Oceanographic research vessels
Parking
Passenger vessels
Passports and visas
Pipeline safety
Pipelines
Railroad employees
Railroad safety
Railroads
Rivers
Seamen
Space transportation and exploration
Traffic regulations
Transportation
Travel
Travel and transportation expenses
Travel restrictions
Vessels
Waterways

BILLING CODE: 1505-02-T

UNITED STATES NUCLEAR REGULATORY COMMISSION

RULES and REGULATIONS

TITLE 10, CHAPTER 1, CODE OF FEDERAL REGULATIONS — ENERGY

NRC SIZE STANDARD

50 FR 20913
Published 5/21/85
Comment period expires 7/22/85.

10 CFR Ch. I

NRC Size Standard for Making Determinations Required by the Regulatory Flexibility Act of 1980

AGENCY: Nuclear Regulatory Commission.

ACTION: Invitation for public comment on proposed definition of small entities.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to adopt a size standard that will be appropriate to use in determining which of the NRC's licensees are small entities. Current NRC practice is to review regulations in accordance with the procedures set out in the Regulatory Flexibility Act of 1980, which requires all Federal agencies to consider the impact of their regulations on small entities. This proposal sets forth for public comment the size determination standard that NRC intends to use to identify more accurately the regulations subject to the regulatory flexibility analysis required by the Act.

ADDRESSES: Interested persons are invited to submit written comments and suggestions on this size standard for a small entity to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch. Copies of comments received by the Commission may be examined and copied for a fee at the Commission's Public Document Room at 1717 H Street NW., Washington, DC.

DATE: Comments should be received on or before July 22, 1985.

FOR FURTHER INFORMATION CONTACT: John Philips, Chief, Rules and Procedures Branch, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone 301-492-7086 or Toll Free 800-368-5642.

SUPPLEMENTARY INFORMATION:

Background and Purpose

The Regulatory Flexibility Act of 1980 requires Federal agencies to consider the effects of their rules on small entities: Small businesses, small governmental jurisdictions, and small not-for-profit organizations. A small business is defined by the Regulatory Flexibility Act and also section 3 of the Small Business Act as a business that is independently owned and operated, and is not dominant in its field. the Small Business Administration (SBA) has established detailed quantitative limits to implement this definition (13 CFR Part 121). A small governmental jurisdiction is one with a population of less than 50,000. In developing NRC's plan to implement the Act, it is possible to apply the Act's definition of small governmental jurisdiction. The third type of small entity is a small not-for-profit organization. The SBA has not defined what a small not-for-profit organization is, and the NRC is not proposing a definition at this time. The NRC would, however, appreciate any views its nonprofit licensees may have on the size of an organization which would constitute a small not-for-profit organization, and the basis for such a determination.

Small Businesses

The SBA size standards for small businesses, revised in 1984 (49 FR 5024; February 9, 1984), are established for distinct industrial categories and do not correspond to NRC licensing categories in which licensees are grouped by their use of specific nuclear materials. To assure definitions of small entities that are appropriate for each agency's particular regulatory programs, the Act permits an agency to establish its own definition of small entities after consultation with SBA's Office of Advocacy and an opportunity for public comment. The NRC has consulted with the SBA's Office of Advocacy, and through this notice, the NRC is seeking public comment on its proposed definition of small entity.

NRC Licensees

Under the Atomic Energy Act, as amended, the NRC is responsible for the licensing and regulation of source, byproduct and special nuclear material in a manner which will protect the public health and safety, national security, and the environment. To this end, the NRC regulates approximately 7,000 licensees who hold over 9,000 licenses. Nuclear reactor licensees, while the focus of wide public interest, represent only a small percentage of the NRC's licensees. The majority of NRC licensees are materials licensees who are engaged in numerous activities involving the use of nuclear material that is regulated by the NRC. These activities include, for example, the following categories: (1) A nuclear medicine department of a hospital where radionuclides may be used for diagnostic purposes through *in vivo* and *in vitro* procedures and for therapeutic applications, such as the treatment of cancer, either by beam therapy or drugs containing radionuclides; (2) A manufacturing or construction firm which uses radionuclides in measuring gauges to perform some type of quality control, such as density gauges in slurry pipeline, thickness gauges in thin film manufacturing, fluid level detectors, and soil density gauges. (3) A university science department where radionuclides are used for teaching and research purposes. (4) A well logging company which would use radionuclides to obtain geological data regarding subsurface formations as an indicator of oil locations. (5) A radiography firm where devices are used to test the integrity of pipelines, weld joints, steel structures, aircraft parts, etc. (6) A manufacturer who might use a cobalt irradiator to sterilize medical products, treat hard woods, plastics or semi-conductor materials, or to test aircraft and electronic equipment.

NRC Licensee Groupings

NRC licensees are grouped into categories in accordance with their use of nuclear material. At the present time, the NRC has categorized its material licensees into about 100 separate groups called program codes. Because these licensees are grouped according to their use of the nuclear material, it is possible to find many industries represented in a given category. For example, the program code that is entitled Measuring Systems-Fixed Gauges contains over 1100 NRC licensees. An analysis of the licensees indicates that they fall into more than 30 Standard Industrial Classification (SIC) Code categories used by the Small Business Administration. Because most of the NRC categories or program codes contain a mixture of industries, it is not possible to align NRC licensees by SIC codes or with SBA size standards which are based on SIC industrial groupings. The inability to match NRC licensees to existing criteria established for determining small entities led the NRC to survey its licensees in order to acquire economic data that would enable the NRC to define a small entity within the nuclear regulatory context. In 1983, the NRC contacted its materials licensees and asked them to complete a questionnaire which requested information such as the number of employees, range of annual receipts, and number of beds (for hospitals). The response rate from the survey, which was conducted during the same period of time that the SBA was preparing its notice of final rulemaking, was in excess of 80 percent.

Evolution of NRC Size Definition

There is no single size standard that applies to all businesses by establishing a precise number of employees or annual receipts. The SBA, in publication of its final rule, established two primary standards. One was based upon number of employees in over 560 industrial groupings that range from a low of 500 employees to a high of 1000 employees, and another was based upon annual receipts for over 260 industrial groupings that range from $0.1 million to $17.0

million. In addition, prior to the publication of its final rule, SBA's smallest employee-based size standard was 25. Through the SBA's publication of its second proposed rule (May 6, 1983; 48 FR 20560), 150 beds was the standard used for a small hospital in the SBA loan program.

Some agencies have adopted criteria that are more consistent with industry practice or the agency mission. The Occupational Safety and Health Administration (OSHA) small business size standard was derived from the clauses imposed in Congressional appropriations, which define a small business as one with 10 or fewer employees. The Civil Aeronautics Board (CAB) uses number of seats and/or payload capacity to determine small air carriers (47 FR 49963; November 4, 1982); the Department of Education uses student population, with differing figures for local educational agencies and institutions of higher education (46 FR 3920; January 16, 1981); and the Securities and Exchange Commission uses a multi-layered approach which takes into consideration capital, assets, revenues (gross), and transactions (47 FR 5215; February 4, 1982).

Based on the wide disparity among the different agency size standards and the unique nature of nuclear regulations, a number of possible methods to set a size standard were assessed by the NRC. These methods and their appropriateness are discussed below. When the NRC designed its questionnaire, it asked licensees to provide information on the actual number of employees, number of beds, and to report annual receipts in 16 dollar ranges.[1]

Use of SBA Size Standards

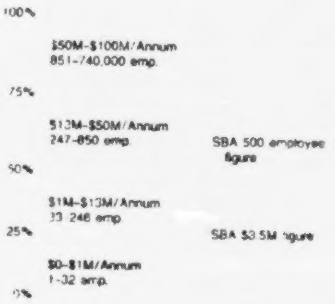
The two most frequently used numbers in the SBA's final rule establishing a size standard are 500 employees and $3.5 million in annual receipts. If the NRC defined a small entity as one with less than 500 employees, approximately 65 percent of its licensees would be small entities under this criterion. When compared to the annual range of billings at the 65 percent figure, this would result in having many companies with annual receipt of between $25 and $50 million being considered small entities. The $3.5 million SBA cut-off figure is almost impossible to apply at this time, because the annual receipts categories that the NRC used in its surveys do not enable the agency to determine specifically which of its licensees fall above or below this cut-off line. Consequently, neither of these criteria is appropriate for NRC use.

Employee Size/Range of Billing—NRC Licensees

At one time, the SBA raised its lowest proposed size standard from 15 to 25 employees (47 FR 18992; May 2, 1982). However, it was found with NRC licensees that a standard with an increased number of employees does not directly correlate to an increase in the annual receipts. For example, if the 25 employee size standard were used, it is possible to find companies with fewer than 25 employees, even fewer than 10 employees, which reported annual receipts greater than $1 million. It is also possible to find licensees with several hundred employees who reported a range of annual receipts the size of the licensees with 25 or fewer employees. Therefore, neither absolute number of employees nor range of annual receipts was viewed as a unique indicator of a small entity among NRC licensees.

The licensees who responded to the NRC questionnaire ranged in size from one employee to 740,000 employees, and they reported annual receipts ranging from less than $75,000 to more than $100,000,000. In searching for natural groupings in the data, it was observed that in both employee size and range of annual receipts, it was possible to group the data by the following quartiles:

NRC GROUPINGS



If the NRC applied the most frequently used SBA size standard of 500 employees, it would fall into the third quartile of NRC licensees and include those licensees whose range of annual receipts would fall between $13M and $50M per year. Using this criterion would result in having approximately 65 percent of NRC's licensees being considered small entities. The NRC believes this result would be contrary to the spirit of the Regulatory Flexibility Act.

If the NRC applied the SBA's most frequently used dollar standard of $3.5M in annual receipts, the line would fall near the bottom of the second quartile of NRC licensees. Based upon the information available to NRC, the NRC concludes that the most logical figure to use, and one which is closest to the $3.5M SBA figure, is the line between the first and second quartile or $1M per year in annual receipts. Thus, $1M in annual receipts was chosen as the threshold figure for determining which NRC licensees are large or small.

NRC Size Definition

The NRC proposes to define a small entity within the nuclear regulatory context as one having annual receipts of $1 million or less. While the agency average of licensees who would be classified as small would be approximately 25 percent, there will be **a variation within each NRC program code in the number of businesses that will be considered to be small. For example, in NRC program code 03110 (Well Logging), 67 of the 127 licensees who responded (52.8 percent) are small entities; in NRC program code 03120 (Other Measuring Systems), where over 2000 licensees responded, 600 (28.8 percent) are small entities; and in NRC program code 02120 (Institutional—Other), which is largely composed of hospitals, 125 (8.5 percent) are small entities. The average figure of 25 percent was chosen across all of NRC's approximately 100 program code to provide a measure of administrative consistency.**

Dated at Bethesda, Maryland this 14th day of May 1985.

For the Nuclear Regulatory Commission.

William J. Dircks,

Executive Director for Operations.

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[1] These was (1) less than 75,000, (2) $75K–$150K, (3) $150K–$500K, (4) more than $500K, (5) less than $250K, (6) $250K–$500K, (7) $500K–$750K, (8) $750K–$1M, (9) $1M–$7M, (10) $7M–$13M, (11) $13M–$19M, (12) $19M–$25M, (13) $25M–$50M, (14) $50M–$75M, (15) $75M–$100M, (16) more than $100M. The first four dollar ranges were used when the radiography licensees were canvassed in April 1983. Based upon experience gained from administering the questionnaire to these licensees, these ranges were revised upward when the remaining licensees were canvassed in July 1983.

PART 0

CONDUCT OF EMPLOYEES

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0.735-50 Use of Government employment.
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Annex A—Code of Ethics for Government Service

Authority: Secs. 25, 161, 68 Stat. 925, 948, as amended (42 U.S.C. 2035, 2201); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); E.O. 11222, 30 FR 6469, 3 CFR 1964–1965 COMP., p. 306; 5 CFR 735.104.

Sections 0.735–21 and 0.735–29 also issued under 5 U.S.C. 552, 553. Section 0.735–26 also issued under secs. 501, 502, Pub. L. 95–521, 92 Stat. 1864, 1867, as amended by secs. 1, 2, Pub. L. 96–28, 93 Stat. 76, 77 (18 U.S.C. 207).

50 FR 25697

Subpart A—General

§ 0.735-1 Policy.

(a) The personnel policy of the U.S. Nuclear Regulatory Commission states, in part, that:

> The Atomic Energy Act requires the Commission to assure itself that the character, association and loyalty of workers in atomic energy are of a high order. Conduct and self-discipline, both on and off the job, must measure up to unusual standards***.

(b) Section 735.101 of the Civil Service Commission regulations (5 CFR 735.101), issued pursuant to Executive Order 11222, May 8, 1965, states that:

> The maintenance of unusually high standards of honesty, integrity, impartiality, and conduct by Government employees and special Government employees is essential to assure the proper performance of the Government business and the maintenance of confidence by citizens in their Government. The avoidance of misconduct and conflicts of interest on the part of Government employees and special Government employees through informed judgment is indispensable to the maintenance of these standards***.

§ 0.735-2 Program objective.

(a) The program objective is to protect the interests of the public and employees by setting forth principles, practices, and standards governing conduct of employees in such a manner that they may be readily understood by the individuals involved and practicably administered by the NRC.

(b) It is expected that the provisions of this part will be observed and administered in a manner which is consistent with both their spirit and their letter.

(c) Of necessity, because of the nature of the criminal statutes and the subject matter involved, this part cannot deal with all of the problems which may arise with regard to the conduct, including conflicts of interest, of employees and former employees.

§ 0.735-3 Responsibilities and authorities.

(a) Employees shall:

(1) Comply with the statutes and the rules, standards of conduct, and other regulations set forth in this part.

(2) Consult the full text of applicable statutes as to whether an action in question may in any way violate the statutes.

31 FR 4502

46 FR 51715

(3) Be guided in all their activities by the Code of Ethics for Government Service (Annex A).

31 FR 4502

(4) Conduct themselves in such a manner as to create and maintain respect for the NRC and the U.S. Government and avoid situations which require or appear to require a balancing of private interests or obligations against official duties.

(5) Be mindful of the high standards of integrity expected of them in all their activities, personal and official.

(6) Not give or appear to give favored treatment or competitive advantage to any member of the public, including former employees of the NRC, appearing before them on their own behalf or on behalf of any nongovernmental interest.

(7) Recognize that violation of any of the instructions or statutes referred to in this part may subject them to disciplinary action by NRC in addition to the penalty prescribed by law for such violation.

(8) Discuss with their immediate supervisor, or counselor, as appropriate, any problem arising out of this part.

46 FR 51715

(9) Report to the Director of their Office all allegations or indications of misconduct, including fraud, graft, corruption, and diversion of NRC assets by NRC or contract employees; however, when the exigencies of the circumstances dictate, employees may make such reports directly to the Office of Inspector and Auditor.

31 FR 4502

(b) Supervisors:

(1) Inform themselves of any problems of their employees arising out of this part, consult with the cognizant NRC counselor as appropriate, and take prompt action to see that the problems, if they cannot be resolved, are referred to higher authority.

(2) Relieve employees from assignments in accordance with § 0.735-22(a).

(c) The Executive Director for Operations assumes responsibilities assigned in §§ 0.735-21(b), 0.735-22(b), 0.735-23(d) and (e), 0.735-26(c) and (d), and 0.735-28.

(d) The Directors of Offices and Divisions. (1) Bring to the attention of appropriate contractors under their jurisdiction those provisions of this part (such as "Future Employment"; "Ex Parte Contacts"; "Assisting Former Employees"; "Gifts, Entertainment, and Favors"; "Cancellation of Contracts"; and others) which may affect the actions of a contractor and his employees in dealing with NRC employees.

46 FR 51715

(2) Report to the Office of Inspector and Auditor all complaints concerning fraud, graft, corruption, diversion of NRC assets by NRC employees or contractors, and misconduct of NRC employees; take action as a result of investigations; and report on action taken, as provided in NRC Manual Chapter 0702, "Notification and Investigation of Misconduct."

40 FR 8774

(3) Assume responsibilities assigned in §§ 0.735-21(b), 0.735-22(b), 0.735-23(d), 0.735-27, 0.735-28, and 0.735-40(b).

(e) The Director, Office of Administration. (1) Provides a copy of this part to each employee and special Government employee, and to each such new employee at the time of his entrance on duty.

(2) Provides a copy of all revisions to each employee and special Government employee.

(3) Brings the provisions of this part to the attention of each employee and special Government employee annually, and at such other times as circumstances warrant.

(4) Assures the availability of counseling services under paragraph (h) of this section to each employee and special Government employee.

46 FR 51715

(5) Has available for review by employees and special Government employees, as appropriate, copies of laws, Executive Order 11222, NRC regulations, and pertinent Office of Personnel Management regulations and instructions relating to ethical and other conduct.

44 FR 62880

(6) Notifies employees and special Government employees at time of entrance on duty and periodically thereafter of the availability of counseling services under paragraph (h) of this section and how and where these services are available.

(f) The Director, Office of Administration, assumes the responsibilities assigned in §§ 0.735-40(b) and 0.735-49.

(g) The Office of Inspector and Auditor investigate all questions of employees' conduct, fraud, etc., in NRC, in accordance with NRC Manual Chapter 0702.

42 FR 20138

(h) The General Counsel.

(1) Is the counselor for NRC.

46 FR 51715

(2) Serves as NRC's designee to the Office of Personnel Management on matters covered by this part.

(3) Designates deputy counselors.

(4) Coordinates counseling services, and assures that counseling and interpretations on questions of conflicts of interest and other matters covered by the part are available to deputy counselors.

(5) Carries out the specific responsibilities assigned in §§ 0.735-27, 0.735-28, and 0.735-49(b).

§ 0.735-4 Definitions.

(a) "Commission" means the Commission of five members or a quorum thereof sitting as a body, as provided by section 201 of the Energy Reorganization Act of 1974, 88 Stat. 1233.

(b) "NRC" means the agency established by Title II of the Energy Reorganization Act of 1974 comprising the members of the Commission and all offices, employees, and representatives authorized to act in any case or matter, whether clothed with final authority or not.

(c) "Employee" means an NRC officer or employee and, insofar as statutory and Executive order restrictions are concerned, a member of the Commission, but does not include (unless otherwise indicated) a special Government employee, or an employee of another Government agency assigned or detailed to the NRC.

(d) "Former employee" means a former NRC officer or employee as defined in paragraph (c) of this section, a former special Government employee, as defined in paragraph (e) of this section, a former member of the Nuclear Regulatory Commission, a former member of the Atomic Energy Commission, and a former officer or employee of the Atomic Energy Commission.

(e) "Special Government employee" means an officer or employee of the NRC who is retained, designated, appointed, or employed to perform, with or without compensation, for not to exceed 130 days during any period of 365 consecutive days, temporary duties either on a fulltime or intermittent basis. The term includes NRC consultants, experts, and members of advisory boards, but does not include a member of the Uniformed Services.

(f) "Official responsibility" means the direct administrative or operating authority, whether intermediate or final, and either exercisable alone or with others, and either personally or through subordinates, to approve, disapprove, or otherwise direct Government action.

(g) "Organization," as used in this part in connection with 18 U.S.C. 208, means universities, foundations, nonprofit research entities and similar nonprofit organizations, States, counties and municipalities and subdivisions thereof as well as business organizations.

(h) "Person" means an individual, a corporation, a company, an association, a firm, a partnership, a society, a joint stock company, or any other organization or institution.

31 FR 4502

(i) [Deleted 40 FR 8774.]

§ 0.735-5 Basic requirements.

(a) *Applicability.* The provisions of this part apply to all current and former NRC employees and special Government employees. Except for § 0.735-28, the provisions of this part are not applicable to employees of other Government agencies assigned or detailed to the NRC. Employees of other Government agencies assigned or detailed to the NRC are required by § 0.735-28 to furnish a statement of employment and financial interest if they are performing duties of a position specified in § 0.735-28(a). However, an employee of another Government agency assigned or detailed to the NRC is not relieved of his responsibilities under regulations or code of conduct prescribed by his parent agency.

40 FR 8774

(b) *Cancellation of contracts.* The Commission reserves the right to declare void, in accordance with law, any contract negotiated or administered in violation of the provisions of NRC regulations, or statute.

(c) *Scope of part.* This part incorporates the statutes, the instructions and specific procedures, pertaining to an employee's conduct.

(d) *Construction of criminal or civil statutes.* The paraphrased version of any criminal or civil statute in this part shall not constitute a binding interpretation thereof upon the NRC or the Federal Government.

(e) *Certifications.* Certifications called for by §§ 0.735-23(e) and 0.735-26(c) and (d), shall be submitted for publication in the FEDERAL REGISTER.

(f) *Disciplinary and other remedial action.* (1) A violation of the regulations in this part by an employee or special Government employee may be cause for appropriate disciplinary action which may be in additon to any penalty prescribed by law.

(2) Remedial action, whether disciplinary or otherwise, shall be effected in accordance with any applicable laws, Executive orders, and regulations.

(g) *Presidential appointees.* Presidential appointees covered by section 401(a) of Executive Order 11222 shall not receive compensation or anything of monetary value for any consultation, lecture, discussion, writing, or appearance the subject matter of which is devoted substantially to the responsibilities, programs, or operations of NRC, or which draws substantially on official data or ideas which have not become part of the body of public information.

31 FR 4502

§ 0.735-6 National emergency application.

The provisions of this part continue in effect without modification in a national emergency.

31 FR 4502

§ 0.735-8 Information collection requirements: OMB approval.

The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). In § 0.735-28, OMB has approved the information collection requirements contained in Form NRC-443, under control number 3150-0025.

49 FR 19623

Subpart B—Conflict of Interest Restrictions

§ 0.735-20 General.

(a) Part I, "Policy," of Executive Order 11222 states:

> Where government is based on the consent of the governed, every citizen is entitled to have complete confidence in the integrity of his government. Each individual officer, employee, or adviser of government must help to earn and must honor that trust by his own integrity and conduct in all official actions.

(b) The elimination of conflict of interest in the Federal service is one of the most important objectives in establishing general standards of conduct. A conflict of interest situation may exist where a Federal employee's private interests, usually of an economic form, conflict, or raise a reasonable question of conflict with his public duties and responsibilities. The potential conflict is of concern whether it is real or only apparent.

(c) An employee, including special Government employee, shall not: (1) Have a direct or indirect financial interest that conflicts substantially, or appears to conflict substantially, with his Government duties and responsibilities; or (2) engage in, directly or indirectly, a financial transaction as a result of, or primarily relying on, information obtained through his Government employment.

31 FR 4502

(d) An employee, including a Special Government employee, is not precluded from having a financial interest or engaging in financial transactions to the

46 FR 51715

same extent as a private citizen not employed by the Government so long as it is not prohibited by the law, Executive Order 11222, Office of Personnel Management regulations, or the regulations in this part.

31 FR 4502

(e) Certain provisions in 18 U.S.C. 201-209, dealing with conflicts of interest in Federal employment are referred to in §§ 0.735-21 through 0.735-27.

§ 0.735-21 Acts affecting a personal financial interest (based on 18 U.S.C. 208).

31 FR 4502

(a) *General.* Except as permitted by paragraphs (b), (c), and (d) of this section, no employee shall participate personally or substantially as a Government officer or employee, through decision, approval, disapproval, recommendation, the rendering of advice, investigation, or otherwise, in a judicial or other proceeding, application, request for a ruling or other determination, contract, claim, controversy, charge, accusation, arrest, or other particular matter in which, to his knowledge, he, his spouse, minor child, partner, organization in which he is serving as officer, director, trustee, partner, or employee, or any person or organization with whom he is negotiating or has any arrangement concerning prospective employment, has a financial interest.

(b) *Granting of ad hoc exemptions.* (1) If an employee desires to request an exemption from the prohibition of paragraph (a) of this section, he shall fully inform the head of his division or office as appropriate, in writing of the nature and circumstances of the particular matter and of the financial interests involved, and shall request a written determination in advance as to the propriety of his participation in such matter.

(2) The head of his division or office, as appropriate, after examining the information submitted, may relieve the employee from participation in the particular matter and so advise him in writing; or, he may approve the employee's participation in such matter upon advising him in writing:

(i) That he has determined the interest is not so substantial as to be deemed likely to affect the integrity of the services which the Government may expect from such officer or employee, and

(ii) That no provision of law and no regulation in this part would appear to be violated by the employee's participation in the particular matter.

(3) When the head of his division or office believes it is inappropriate for him to make a determination as provided in subparagraph (2) of this paragraph, he shall forthwith submit the information with his recommendation through channels to the Executive Director for Operations, who shall make a determination as provided in subparagraph (2) of this paragraph, forwarding the original of his determination to the submitting official and a copy to the employee involved.

(4) A copy of each request and response made under the provisions of subparagraphs (1) and (2) of this paragraph shall be forthwith forwarded through channels to the Executive Director for Operations as a matter of record. Copies of all documents referred to in subparagraphs (1), (2), and (3) of this paragraph shall be filed by the holders thereof in their confidential files.

(5) Whenever it can be reasonably anticipated that there will be a need to invoke these procedures repeatedly, and where it also appears that a burden would be placed on the NRC thereby, consideration should be given by the head of his division or office to dismissal or transfer of the employee to another position where the problems will not arise, or to the elimination of the outside interest creating the difficulty. It is expected that the employee concerned will take the initiative in resolving any problem in this area.

31 FR 4502

44 FR 41422

(c) *Exemption of remote or inconsequential financial interests.*—(1) In accordance with the provisions of 18 U.S.C. 208(b)(2) the NRC has exempted the following financial interests from paragraph (a) of this section and from the requirements of paragraph (b) of this section, upon the ground that such interests are too remote or too inconsequential to affect the integrity of its employees' services:

(i) Financial interests in an enterprise in the form of shares in the ownership thereof, including preferred and common stocks whether voting or nonvoting, and warrants to purchase such shares;

(ii) Financial interests in an enterprise in the form of bonds, notes, or other evidence of indebtedness;

(iii) Investments in State or local government bonds and investments in shares of a widely held diversified mutual fund or regulated investment company, except holdings in mutual investment funds or regulated investment companies dealing primarily in atomic energy stocks;

Provided, That in the case of subdivisions (i) and (ii) of this subparagraph:

(A) The total market value of the financial interests described in said subdivisions with respect to any individual enterprise does not exceed $1000; and

(B) the holdings in any class of shares, or bonds, or other evidences of indebtedness, of the enterprise do not exceed 1 percent of the dollar value of the outstanding shares, or bonds or other evidences of indebtedness in said class.

44 FR 41422

31 FR 4502

(2) Where a person covered by this exemption is a member of a group organized for the purpose of investing in equity or debt securities, the interest of such person in any enterprise in which the group holds securities shall be based upon said person's equity share of the holdings of the group in that enterprise.

(3) For purposes of subparagraph (1) of this paragraph, computations of dollar-value of financial interests in corporation shall be by means of:

(i) Market value in the case of stocks listed on national exchanges; or

(ii) Over-the-counter market quotations as reported by the National Daily Quotation Service in the case of unlisted stocks; or

(iii) By means of net book value (i.e. assets less liabilities) in the case of stocks not covered by the preceding two categories.

With respect to debt securities, face value shall be used for valuation purposes.

(4) The dollar value and percentage of financial interests listed above in subparagraph (1) of this paragraph shall be computed as of the date on which the employee first participated personally and substantially in any particular matter, within the meaning of 18 U.S.C. 208(a), relating to the enterprise concerned. The dollar value and percentage so computed shall govern during the entire period that the employee participates in the particular matter unless, after the aforesaid date of computation, he, or other person or organization referred to in paragraph (a) of this section, acquires an additional interest in the same enterprise. In the event of such subsequent acquisition, the dollar value and percentage shall be recomputed as of the date of such acquisition. If, in such case, the dollar value and percentage computed exceeds the limitations described in subparagraph (1) of this paragraph, the general exemption

provided therein shall no longer be applicable and an ad hoc exemption must be sought in accordance with paragraph (b) of this section.

(d) *Special exemption for special Government employees.* Federal Personnel Manual Chapter 735, Appendix C provides that a special Government employee should in general be disqualified from participating as such in a matter of any type the outcome of which will have a direct and predictable effect upon the financial interests covered by 18 U.S.C. 208. However, that chapter states that the power of exemption may be exercised in this situation "if the special Government employee renders advice of a general nature from which no preference or advantage over others might be gained by any particular person or organization." It is the policy of the Nuclear Regulatory Commission in conformity with the foregoing, to exercise the power of exemption pursuant to 18 U.S.C. 208(b) in such situations. The authority to grant such an exemption is delegated to the NRC official responsible for appointment or designation of the particular consultant or advisor. This exemption is noted on the form NRC-443 by the appointing official for the consultant or advisor concerned, by a statement that the employee "need not be precluded from rendering general advice in situations where no preference or advantage over others might be gained by any particular person or organization."

§ 0.735-22 Future employment (based on 18 U.S.C. 208).

(a) Solicitation, negotiation, or arrangements for private employment by an employee who is acting on behalf of the NRC in any particular matter in which the prospective employer has a financial interest are prohibited. With the authorization of his supervisor, an employee may be relieved of any assignment which, in the absence of such relief, might preclude such solicitation, negotiation, or arrangements.

(b) No employee shall undertake to act on behalf of the NRC in any capacity in a matter that to his knowledge affects even indirectly any party outside the Government with whom he is soliciting, negotiating, or has arrangements for future employment, except pursuant to the authorization of the Commission, its designee, or the Executive Director for Operations, as appropriate, after full disclosure. (See § 0.735-21.)

§ 0.735-23 Activities of officers and employees in claims against and other matters affecting the Government (based on 18 U.S.C. 205).

(a) No employee shall otherwise than in the proper discharge of his official duties:

(1) Act as agent or attorney for prosecuting any claim against the United States, or receive any gratuity, or any share of or interest in any such claim in consideration of assistance in the prosecution of such claim, or

(2) Act as agent or attorney for anyone before any department, agency, court, court-martial, officer, or any civil, military, or naval commission in connection with any proceeding, application, request for a ruling or other determination, contract, claim, controversy, charge, accusation, arrest, or other particular matter in which the United States is a party or has a direct and substantial interest.

(b) A special Government employee shall be subject to paragraph (a) of this section only in relation to a particular matter involving a specific party or parties (1) in which he has at any time participated personally and substantially as a Government employee or as a special Government employee through decision, approval, disapproval, recommendation, the rendering of advice, investigation or otherwise, or (2) which is pending in the department or agency of the Government in which he is serving: *Provided,* That subparagraph (2) of this paragraph shall not apply in the case of a special Government employee who has served in such department or agency no more than 60 days during the immediately preceding period of 365 consecutive days.

(c) Nothing in paragraph (a) of this section prevents an employee, if not inconsistent with the faithful performance of his duties, from acting without compensation as agent or attorney for any person who is the subject of disciplinary, loyalty, or other personnel administration proceedings in connection with those proceedings.

(d) Nothing in paragraph (a) of this section prevents an employee from acting, with or without compensation, as agent or attorney for his parents, spouse, child, or any person for whom, or for any estate for which, he is serving as guardian, executor, administrator, trustee, or other personal fiduciary except in those matters in which he has participated personally and substantially as a Government employee, through decision, approval, disapproval, recommendation, the rendering of advice, investigation, or otherwise, or which are the subject of his official responsibility, provided that the Commission, its designee, the Executive Director for Operations, or the head of an office or division, as appropriate, approves.

(e)(1) Nothing in paragraph (a) of this section prevents a special Government employee from acting as agent or attorney for another person in the performance of work under a grant by, or a contract with or for the benefit of, the United States when presented by the NRC provided that the Executive Director for Operations shall certify in writing that the national interest so requires. Such certification shall be submitted for publication in the FEDERAL REGISTER.

(2) The special Government employee shall immediately notify the NRC when so designated to act as agent or attorney by his private employer.

(f) Nothing in paragraph (a) of this section prevents an employee from giving testimony under oath or from making statements required to be made under penalty for perjury or contempt.

§ 0.735-24 Receiving salary from source other than the U.S. Government (based on 18 U.S.C. 209).

(a) No employee shall receive any salary, or any contribution to or supplementation of salary, as compensation for his services as an employee of the NRC from any source other than the Government of the United States, except as may be contributed out of the treasury of any State, county, or municipality.

(b) Nothing in paragraph (a) of this section prevents an employee of the NRC from continuing to participate in a bona fide pension, retirement, group life, health or accident insurance, profit sharing, stock bonus, or other employee welfare or benefit plan maintained by a former employer.

(c) Paragraph (a) of this section does not apply to a special Government employee or to an employee of the Government serving without compensation, whether or not he is a special Government employee.

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(d) Paragraph (a) of this section does not prohibit acceptance of contributions, awards, or other expenses for training or to attend meetings under the terms of chapter 41 of title 5, United States Code. See NRC Appendix 4150.

32 FR 13658

§ 0.735-25 Compensation to employees in matters affecting the Government (based on 18 U.S.C. 203).

(a) No employee shall, otherwise than as provided by law for the proper discharge of official duties, directly or indirectly receive or agree to receive, or ask, demand, solicit, or seek, any compensation for any services rendered or to be rendered either by himself or another in relation to any proceeding, application, request for a ruling or other determination, contract, claim, controversy, charge, accusation, arrest, or other particular matter in which the United States is a party or has a direct and substantial interest, before any department, agency, court-martial, officer, or any civil, military, or naval commission.

(b) A special Government employee shall be subject to paragraph (a) of this section only in relation to a particular matter involving a specific party or parties (1) in which he has at any time participated personally and substantially as a Government employee or as a special Government employee through decision, approval, disapproval, recommendation, the rendering of advice, investigation, or otherwise, or (2) which is pending in the department or agency of the Government in which he is serving: *Provided*, That subparagraph (2) of this paragraph shall not apply in the case of a special Government employee who has served in such department or agency no more than 60 days during the immediately preceding period of 365 consecutive days.

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§ 0.735-26 Disqualification of former officers and employees in matters connected with former duties or official responsibilities; disqualification of partners of current officers and employees (based on 18 U.S.C. 207).

(a) No employee, after terminating NRC employment, shall knowingly act as agent or attorney for, or otherwise represent, any other person (except the United States) in any formal or informal appearance before, or, with the intent to influence, make any oral or written communication on behalf of any other person (except the United States) to:

(1) any department, agency, court, courtmartial, or any civil, military or naval commission of the United States or the District of Columbia, or any officer or employee thereof, and

(2) in connection with any judicial or other proceeding, application, request for a ruling or other determination, contract, claim, controversy, investigation, charge, accusation, arrest, or other particular matter involving a specific party or parties in which the United States or the District of Columbia is a party or has a direct and substantial interest, and

(3) in which the individual participated personally and substantially as an employee through decision, approval, disapproval, recommendation, the rendering of advice, investigation or otherwise, while so employed.

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(b)(1) No employee shall, within two years after terminating NRC employment, knowingly act as agent or attorney for, or otherwise represent, any other person (except the United States), in any formal or informal appearance before, or, with the intent to influence, make any oral or written communication on behalf of any other person (except the United States) to:

(i) any department, agency, court, courtmartial, or any civil, military or naval commission of the United States or the District of Columbia, or any officer or employer thereof, and

(ii) in connection with any judicial or other proceeding, application, request for a ruling or other determination, contract, claim, controversy, investigation, charge, accusation, arrest or other particular matter involving a specific party or parties in which the United States or the District of Columbia is a party or has a direct and substantial interest, and

(iii) which was actually pending under the individual's official responsibility as an employee within a period of one year prior to the termination of such responsibility.

(2) No employee shall, within two years after terminating NRC employment, as specified in paragraph (d) of this section, knowingly represent, or aid, counsel, advise counsel or assist in representing any other person (except the United States) by personal presence at any formal or informal appearance before:

(i) any department, agency, court, courtmartial, or any civil, military or naval commission of the United States or the District of Columbia, or any officer or employer thereof, and

(ii) in connection with any judicial or other proceeding, application, request for a ruling or other determination, contract, claim, controversy, investigation, charge, accusation, arrest or other particular matter involving a specific party or parties in which the United States or the District of Columbia is a party or has a direct and substantial interest, and

(iii) in which the individual participated personally and substantially as an employee.

(c) No employee, other than a special Government employee who serves for less than sixty days in a given calendar year, having been employed as specified in paragraph (d) of this section, shall, within one year after termination of NRC employment, knowingly act as agent or attorney for, or otherwise represent, anyone other than the United States in any formal or informal appearance before, or, with the intent to influence, make any oral or written communication on behalf of anyone other than the United States, to:

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(1) the Nuclear Regulatory Commission, and

(2) in connection with any judicial, rulemaking, or other proceeding, application, request for a ruling or other determination, contract, claim, controversy, investigation, charge, accusation, arrest, or other particular matter, and

(3) which is pending before the Commission or in which the Commission has a direct and substantial interest.

(d)(1) Paragraph (c) of this section applies to a person employed:

(i) at a rate of pay specified in or fixed according to Subchapter II of Chapter 53 of Title 5, United States Code, or a comparable or greater rate of pay under other authority, or

(ii) in a position which involves significant decision-making or supervisory responsibility, as designated by the Director of the Office of Government Ethics, in consultation with the Commission. Only positions for which the basic rate of pay for GG–17 of the General Schedule prescribed by section 5332 of Title 5, United States Code, or positions which are established within the Senior Executive Service pursuant to the Civil Service Reform Act of 1978 may be designated.

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(2) The prohibition of paragraph (c) of this section shall not apply to appearances, communications, or representation by a former employee, who is:

(i) an elected official of a State or local government, or

(ii) whose principal occupation or employment is with (A) an agency or instrumentality of a State or local government, (B) an accredited, degree-granting institution of higher education, as defined in section 1201(a) of the Higher Education Act of 1965, or (C) a hospital or medical research organization, exempted and defined under section 501(c)(3) of the Internal Revenue Code of 1954, and the appearance, communication, or representation is on behalf of such government, institution, hospital, or organization.

50 FR 25697

➢ (e) The prohibitions of paragraphs (a), (b), and (c) of this section shall not apply—

(1) With respect to the making of communications solely for the purpose of furnishing scientific or technological information if the following procedures are observed:

(i) The former employee proposing to make the communication solely for the purpose of furnishing scientific or technological information receives prior written authorization from the Executive Director for Operations. The individual shall provide to the Executive Director for Operations a written statement that indicates he or she is a former employee subject to post-employment restrictions under this section, that briefly summarizes the content of the proposed communication, that describes his or her involvement, if any, as an NRC employee on the matter to be discussed, and that certifies the communication he or she desires to make is solely for the purpose of furnishing scientific or technological information; and

(ii) The Executive Director for Operations before deciding whether to authorize the communication shall consult with the counselor or deputy counselor. The primary factor to be considered by the Executive Director for Operations is whether receipt of the scientific or technological information would further the agency's mission.

(2) If the Commission, in consultation with the Director of the Office of Government Ethics, makes a certification published in the **Federal Register** that the former employee has outstanding qualifications in a scientific, technological, or other technical discipline, and is acting with respect to a particular matter which requires such qualifications, and that the national interest would be served by the participation of the former officer or employee. The Commission under this provision may authorize communications that are not limited to transmission of scientific or technological information.

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(f) A partner of an NRC employee, including a special government employee, shall not act as agent or attorney for anyone other than the United States before any department, agency, court, court-martial, or any civil, military, or naval commission of the United States or the District of Columbia, or any officer or employee thereof, in connection with any judicial or other proceeding, application, request for a ruling or other determination, contract, claim, controversy, investigation, charge, accusation, arrest, or other particular matter in which the United States or District of Columbia is a party or has a direct and substantial interest, and in which such employee participates or has participated personally and substantially as an employee through decision, approval, disapproval, recommendation, the rendering of advice, investigation, or otherwise, or which is the subject of his official responsibility.

(g) Nothing in this section shall prevent a former employee from giving testimony under oath, or from making statements required to be made under penalty of perjury.

(h) The prohibition contained in paragraph (c) of this section shall not apply to appearances or communications by a former employee concerning matters of a personal and individual nature, such as personal income taxes or pension benefits; nor shall the prohibition of that subsection prevent a former employee from making or providing a statement, which is based on the former employee's own special knowledge in the particular area that is the subject of the statement, provided that no compenstion is thereby received, other than that regularly provided for by law or regulation for witnesses.

(i) If the Commission finds, after notice and opportunity for a hearing, that the former employee violated paragraph (a), (b), or (c) of this section, the Commission may prohibit that person from making on behalf of any other person (except the United States), any informal or formal appearance before, or, with the intent to influence, any oral or written communication to, the Commission on a pending matter of business for a period not to exceed five years, or may take other appropriate disciplinary action. Such disciplinary action shall be subject to review in an appropriate United States district court. The Commission's procedures for implementing this subsection are contained in NRC Manual Chapter 4124.

(j) The Office of Personnel Management has promulgated detailed regulations explaining and interpreting the post-employment regulations set forth in this section. See 5 Code of Federal Regulations Part 737.

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§ 0.735-27 Appearances by former employees before NRC.

When a former employee proposes to act as agent or attorney before an NRC office on behalf of anyone other than the United States in connection with any of the matters cited in § 0.735-26, he is expected to make known to the appropriate official of the NRC office the fact of his former assignment with NRC. The head of the office or division or employee before whom the former employee appears, before transacting business with the former employee or authorizing employees under his jurisdiction to transact any business with the former employee, shall call the former employee's attention to the restrictions and penalties contained in 18 U.S.C. 207. No NRC official or employee, except the General Counsel, shall offer to the former employee an interpretation of 18 U.S.C. 207 as applied to the situation at hand.

45 FR 26022

§ 0.735-28 Confidential statements of employment and financial interests.

(a) *Categories of employees required to submit statements.* The following employees shall submit confidential statements of employment and financial interest prepared in accordance with paragraph (c) of this section. These employees have duties and responsibilities which require the incumbent to report employment and financial interests in order to avoid involvement in a possible conflicts of interest situation, to protect the integrity of the government, and to carry out the purposes of the federal laws, executive orders and regulations pertaining to conflicts of interest.

(1) All employees paid at the levels of GG–13, GG–14, or GG–15.

(2) All employees occupying professional staff positions in the Office of Policy Evaluation, all contracting officers in the Office of Administration, and all attorneys in the Offices of the General Counsel and Executive Legal Director (including those employees being paid below the GG–13 level).

(3) All special Government employees except those who have worked 60 days or more in the previous calendar year and were paid during that period at a level of GG–16 or above, or an equivalent thereto.

(b) *Notice of employees of time and place to submit statements.* Upon

commencing NRC employment, the Office of Administration will provide all employees covered by the reporting requirement with a copy of the statement form. Each employee covered by the reporting requirement shall submit his statement to the head of his office not later than 30 days after his entrance on duty. Statements of special Government employees shall be submitted prior to appointment. Each regular and special Government employee covered by the reporting requirement shall submit to the head of his office a supplementary annual statement by May 15 of each year. The information provided in this annual supplement should reflect the individual's interests as of April 30. Notwithstanding the filing of the report(s) required by this section, each employee shall at all times avoid acquiring a financial interest that could result, or taking an action that would result, in a violation of the conflicts-of-interest provisions of section 208 of title 18, United States Code, or this Part 0.

45 FR 26022

(c) *Preparation of statement.* Statements shall be prepared in accordance with the following:

(1) *Statement Form.* The forms prescribed by NRC are:

Regular Government employees—Form NRC 269.
Special Government employees—Form NRC 443.

(2) *Statement content*—(i) *Interests of employee's relatives.* The interest of a spouse, minor child, or other member of an employee's immediate household is considered to be an interest of the employee and must be reported. For the purpose of this paragraph, "member of an employee's immediate household" means full-time residents of the employee's household.

(ii) *Information not known by employees.* If any information required to be included on the statement or supplementary statement, including holdings placed in trust, is not known to the employee but is known to another person, the employee shall request that other person to submit information on his behalf, and shall report such request in Part IV of Form NRC 269 or item 16b. of Form NRC 443.

(iii) *Information not required to be submitted.* A statement or supplementary statement need not contain the following:

(A) Any information relating to the employee's connection with, or interest in, a professional society or a charitable, religious, social, fraternal, recreational, public service, civic, or political organization or a similar organization not conducted as a business enterprise and which is not engaged in the ownership or conduct of a business enterprise. For the purpose of this section, educational and other institutions doing research and development or related work involving grants of money from or contracts with the Government are deemed "business enterprises" and are required to be included in an employee's statement.

(B) Precise amounts of financial interests, indebtedness, or value of real property. The employee may, however, at a later time be required to reveal precise amounts if the NRC needs that information in order to carry out its responsibilities under applicable laws and regulations.

(C) Remote or inconsequential financial interests, as set forth in § 0.735–21(c).

(D) For special Government employees: Those financial interests which are determined by the official responsible for such employee's appointment as not to be related either directly or indirectly to the duties and responsibilities of said employee.

(d) *Reviewing statements and reporting conflicts of interest.*

(1) The employee shall prepare the statement in duplicate, retain one copy, and submit one copy to the head of his office.

(2) The office head, in reviewing the statement, shall assess it for conflicts or the appearance of conflicts of interest in the context of the employee's assigned duties and responsibilities in the NRC.

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(3) If the office head desires advice and guidance, he may discuss the statement with the counselor or appropriate deputy counselor.

(4) The office head shall discuss with the employee and point out any aspects of the statement which give rise, in the office head's opinion, to questions of conflict or of appearance of conflict. (The office head shall not take, or direct the employee to take, any action with respect to such conflict without first seeking the advice of the counselor or appropriate deputy counselor.)

(5) The office head shall in all cases record his opinion as to the presence or absence of a conflict on the statement and forward same to the NRC counselor or deputy counselor.

(6) The NRC counselor or deputy counselor shall review the statement, and discuss any questions with the employee and/or his respective office head.

(7) If the NRC counselor or deputy counselor believes that the statement evidences no question of conflict of interest, he shall record his opinion on the statement, and notify the office head.

(8) If the NRC counselor or deputy counselor believes there is a question of conflict of interest, he shall return the statement to the office head with his opinion recorded thereon. (The counselor or deputy counselor shall make his services available to the office head and employee involved to assist in effecting a resolution of any conflict or appearance of conflict.) The reviewer shall report to the counselor or deputy counselor the results of endeavors to effect resolution of the conflict at the employee-office head level, which results shall be recorded on the employee's statement and submitted to the counselor or deputy counselor for review and approval.

(9) When a statement submitted or information from other sources indicates a conflict between the interests of an employee and the performance of his service for the NRC and when the conflict or appearance of conflict is not resolved by the head of the employee's office, or the counselor or deputy counselor, the information concerning the conflict or appearance of conflict shall be reported to the Commission, or the Executive Director for Operations, as appropriate. The employee concerned shall be provided an opportunity to explain the conflict or appearance of conflict.

(10) When, after consideration of the explanation of the employee provided for in paragraph (d)(9) of this section, the Commission, or the Executive Director for Operations, as appropriate, decides that remedial action is required, immediate action to end the conflict or appearance of conflict of interest shall be taken. Remedial action may include, but is not limited to:

(i) Changes in assigned duties;

(ii) Divestment by the employee of his conflicting interest;

(iii) Disciplinary action; or

(iv) Disqualification for a particular assignment.

Remedial action, whether disciplinary or otherwise, shall be effected in accordance with any applicable laws, Executive Orders, and regulations. Disciplinary remedial action with respect to an employee of another Government agency assigned or detailed to the NRC shall be effected only by the parent agency.

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(11) Upon completion of processing, the statement shall be filed in the office of the counselor or deputy counselor, in a special file maintained for that purpose. An NRC office may request a copy of a statement from the counselor or deputy counselor: *Provided,* That it is required for purposes of carrying out responsibilities under this part.

(12) The required supplementary statements shall be processed in the same manner as an initial statement.

(e) *Confidentiality of employees' statements.* NRC shall hold each statement of employment and financial interests, and each supplementary statement, in confidence. To insure this confidentiality only the NRC counselor, deputy counselor(s), and those office heads to whom reports are to be submitted (including those employees specifically designated by them to assist in the review as may be necessary) are authorized to review the statements as provided in this section. The foregoing employees are responsible for maintaining the statements in confidence and shall not allow access to, or allow information to be disclosed from, a statement except to carry out the purpose of this part. NRC shall not disclose information from a statement except in accordance with procedures set forth in paragraph (d) of this section, or as the Commission, or the Executive Director for Operations, as appropriate, or the Office of Personnel Management shall determine for good cause shown.

(f) *Effect of employee's statements on other requirements.* The statements of employment and financial interests and supplementary statements required of employees are in addition to, and not in substitution for, or in derogation of, any similar requirement imposed by law, order, or regulation. The submission of a statement or supplementary statement by an employee or the absence of any requirement that an employee submit such a statement does not permit him or any other person to participate in a matter in which his or the other person's participation is prohibited by law, order, or regulation.

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(g) *Availability of review.* Any employee who believes that his position has been improperly included under this section as one requiring the submission of a statement of employment and financial interests may submit a grievance. A non-bargaining unit employee must use the grievance procedure in NRC Manual Chapter 4157 for review of the complaint. A bargaining unit employee must use the grievance procedure negotiated with the National Treasury Employees Union.

46 FR 51715

§ 0.735-28a Financial disclosure reports under the Ethics in Government Act.

Commissioners, employees and special government employees paid at or above the grade 16 level, and employees whose positions are excepted from the regular competitive appointment process by reason of being of a confidential or policymaking character (unless otherwise excluded by the Office of Government Ethics) shall file public financial disclosure reports (SF 278) in accordance with the requirements of the Ethics in Government Act and regulations of the Office of Government Ethics, 5 CFR Part 734. The employees shall submit their completed forms to the Office of the General Counsel for review. The General Counsel's office shall place the form in the Commission's Public Document Room.

50 FR 25697

§ 0.735-29 Restriction against ownership of certain security interests by Commissioners, certain staff members and other related personnel

(a) No Commissioner or employee, including special government employees who are members of the Advisory Committee on Reactor Safeguards, the Atomic Safety and Licensing Board Panel or the Atomic Safety and Licensing Appeal Panel, who occupies a position at or above GS-13 or its equivalent, shall own any stocks, bonds, or other security interests issued by any entity falling within the categories set forth in paragraph (b)(1) of this section. This prohibition also applies to employees who occupy positions below the GS-13 level that fall within occupational codes designated by the Commission. The restrictions set forth in this section apply to spouse, minor child, or other members of the immediate household of a Commissioner, employee, or special government employee. In cases where the entity covered by the prohibition is a subsidiary of another corporation, the prohibition extends to the parent company.

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(b) The Commission will publish at least once each year a list of stocks, bonds, and other security interests which employees covered by this section may not own.

50 FR 25697

(1) These are stocks, bonds, or other security interests issued by:

(i) Publicly or privately owned utilities which have filed an application with the Commission requesting an early site review, or seeking authorization to construct or operate a facility for the generation of electric energy by means of a nuclear reactor and those utilities which have received a construction permit or an operating license from the Commission that is currently effective.

(ii) State or local governments, if the primary purpose of the security is to finance the construction or operation of a nuclear reactor.

(iii) Companies manufacturing or selling nuclear power or test reactors.

(iv) Architectural-engineering companies that have been engaged to provide services relating to a nuclear facility by an applicant for a construction permit or an applicant for an operating license, and architectural-engineering companies which have filed a standard reference design that is under Commission review or has been approved by the Commission and is currently effective.

(v) Companies licensed by the Commission to mill, convert, enrich, fabricate, store, or dispose of source or special nuclear material, or applicants for such licenses.

(2)(i) An individual covered by this section who owns securities described in paragraph (a)(1) of this section shall dispose of them no later than 365 days after the entities first appear on the list described in paragraph (a) of this section. Notwithstanding the provisions of § 0.735-21(c), no employee may participate personally and substantially in a particular matter affecting any entity that appears on the list as long as the employee or his spouse, minor child, or other members of his immediate household owns the security interest.

(ii) An individual newly employed by NRC who is covered by this section shall dispose of any securities described in paragraph (a)(1) of this section that the employee may own no later than 30 days after his entrance on duty and within the same period shall ensure and sign a certification that neither the employee nor any individual who is covered by this section through relationship with him owns any securities described in that paragraph.

(c) Each individual employed by NRC who is covered by this section shall each year sign either (1) a certification that neither he nor any individual covered by this section through relationship with him owns any securities described in paragraph (a)(1) of this section or, if he or any such individual in fact owns securities therein described, (2) a certification identifying them, disclosing how and when they were acquired and stating approximately when they will be disposed of.

(d) Securities described in paragraph (b)(1) of this section that are acquired by an individual who is covered by this section through gift, inheritance or other similar involuntary manner shall be disposed of within a reasonable time.

(e) The Commission may exempt an employee from the restrictions of this section where divestiture of the stock, bond, or other security interest is determined to be inequitable by the Commission.

44 FR 41422

Subpart C—Other Restrictions Imposed by Statute on Conduct of Employees

§ 0.735-30 Description of statutory provisions.

Each employee has a positive duty to acquaint himself with each statute that relates to his ethical and other conduct as an employee of the NRC and the Government. Certain of these statutes are referred to in §§ 0.735-21–0.735-27. Attention of employees is also directed to the following statutory provisions:

(a) The prohibitions contained in the following sections of the Atomic Energy Act of 1954, as amended: Section 222, "Violation of Specific Sections"; Section 223, "Violation of Sections Generally"; Section 224, "Communication of Restricted Data"; Section 225, "Receipt of Restricted Data"; Section 226, "Tampering With Restricted Data"; and Section 227, "Disclosure of Restricted Data" (42 U.S.C. 2272 through 2277).

(b) The prohibitions against the disclosure of classified information (18 U.S.C. 798, 50 U.S.C. 783).

(c) The prohibition against the disclosure of confidential information (18 U.S.C. 1905).

(d) The prohibition against the employment of a member of a Communist organization (50 U.S.C. 784).

(e) The prohibition against lobbying with appropriated funds (18 U.S.C. 1913).

(f) The prohibition against proscribed political activities in subchapter III of chapter 73 of title 5, United States Code and 18 U.S.C. 602, 603, 607, and 608. (See NRC Manual Chapter 4122, "Political Activity.")

(g) The prohibition against bribery of public officials and witnesses (18 U.S.C. 201).

(h) The prohibition against acceptance of solicitation to obtain appointive public office (18 U.S.C. 211).

32 FR 13650

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(i) The prohibitions against disloyalty and striking (5 U.S.C. 7311, 18 U.S.C. 1918). (See also NRC Manual Chapter 4121, "Oath of Office" and NRC Manual Chapter 4166, "Labor-Management Relations Program for Federal Employees.")

32 FR 13650

(j) The provision relating to the habitual use of intoxicants to excess (5 U.S.C. 7352).

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(k) The prohibition against the misuse of a Government vehicle (31 U.S.C. 638a(c)).

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(l) The prohibition against the misuse of the franking privilege (18 U.S.C. 1719).

(m) The prohibition against the use of deceit in an examination or personnel action in connection with Government employment (18 U.S.C. 1917).

(n) The prohibition against fraud or false statements in a Government matter (18 U.S.C. 1001).

(o) The prohibition against mutilating or destroying a public record (18 U.S.C. 2071). (See also NRC Appendix 0230, "Records Disposition.")

(p) The prohibition against counterfeiting and forging transportation requests (18 U.S.C. 508).

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(q) The prohibition against embezzlement of Government money or property (18 U.S.C. 641). (See also NRC Manual Chapter 5201, "Personal Property Management.")

32 FR 13650

(r) The prohibition against failing to account for public money (18 U.S.C. 643).

(s) The prohibition against an employee's private use of public money (18 U.S.C. 653).

(t) The prohibition against embezzlement of the money or property of another person in the possession of an employee by reason of his employment (18 U.S.C. 654).

(u) The prohibition against unauthorized use of documents relating to claims from or by the Government (18 U.S.C. 285).

(v) The prohibition against making false entries in official records with intent to defraud or making false reports concerning moneys and securities with such intent (18 U.S.C. 2073).

(w) The prohibition against an employee acting as the agent of a foreign principal registered under the Foreign Agents Registration Act (18 U.S.C. 219).

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(x) The Code of Ethics for Government Service (5 U.S.C. 7301).

31 FR 4502

Subpart D—Restrictions Imposed by NRC Administrative Decision on Conduct of Employees

42 FR 38893

§ 0.735-40 Outside employment and other outside activity.

(a) There is no general prohibition against employees engaging in outside employment or other outside activity; except that no employment or activity may be undertaken which is not compatible with the full and proper discharge of the duties and responsibilities of the employee's Government employment. Incompatible activities include but are not limited to:

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(1) Acceptance of a fee, compensation, gift, payment of expense, or any other thing of monetary value in circumstances in which acceptance may result in, or create the appearance of, conflicts of interests; or

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(2) Acceptance of any employment, fee, compensation, or payment of expense, from (i) A Commission licensee; (ii) an applicant for Commission license; (iii) an organization directly engaged in activities in the commercial nuclear field; (iv) a Commission contractor; (v) a Commission supplier; (vi) holder of a license issued by a State pursuant to an agreement between the Commission and the State; (vii) a trade association which represents clients concerning nuclear matters; or (viii) a law firm or other organization which is participating in an NRC proceeding or which regularly represents itself or clients before the NRC, unless written authorization is received pursuant to § 0.735-40(b). Ordinarily, an employee will be authorized to serve as an instructor at an academic institution which holds a Commission license, or to engage in other proposed activities of a similar character.

42 FR 38893

(3) Outside employment which tends to impair his mental or physical capacity to perform his Government duties and responsibilities in an acceptable manner.

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(b) In any case in which there is a question as to the propriety of outside employment in which an employee proposes to engage, or where prior written authorization is required pursuant to § 0.735-40(a)(2), the employee's office or division head shall prepare and transmit the following information to the appropriate individual(s) specified in paragraph (f) of this section: (1) Name and job title of the employee involved; (2) A brief summary of the employee's official NRC duties; (3) A brief description of the proposed employment or outside activity, including the compensation to be received; (4) The name and nature of the business of the employing individual or organization; (5) His views whether the outside employment or activity should be authorized.

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(c) An employee shall not receive any salary or anything of monetary value from a private source as compensation for his services to the Government (18 U.S.C. 209).

46 FR 51715

(d) Employees are encouraged to engage in teaching, lecturing, and writing that is not prohibited by law, Executive Order 11222, Office of Personnel Management regulations, or the regulations in this part. However, an employee shall not, either for or without compensation, engage in teaching, lecturing, or writing, including teaching, lecturing, or writing for the purpose of the special preparation of a person or class of persons for an examination of the Office of Personnel Management or Board of Examiners for the Foreign Service, that is dependent on information obtained as a result of his Government employment, except when that information has been made available to the general public or will be made available on request, or when the Executive Director for Operations has given written authorization for the use of nonpublic information on the basis that the use is in the public interest.

(e) Except as allowed for training or to attend meetings under section 4111 of title 5, United States Code, and Executive Order 10800, no employee shall accept a fee from an outside source on account of a public appearance, a speech, or lecture, if the public appearance or the preparation or delivery of the speech or lecture was a part of the official duties of the employee, if the public appearance, the speech, or the lecture was made during official working hours, or if travel for the purpose of the public appearance, speech, or lecture was made at Government expense. In addition, no employee shall accept a fee for the preparation, publication, or review of an article, story, or book if it was prepared during official working hours and/or was a part of the official duties of the employee.

32 FR 13650

(f) Employees of offices reporting to the Commission through the Executive Director for Operations must receive the written authorization of the Executive Director for Operations before engaging in activities covered by paragraphs (a)(2) and (b) of this section. The Executive Director for Operations before making his decision shall consult with the head of the employee's office or division and with the counselor or deputy counselor. Employees of boards, panels, and offices reporting directly to the Commission must receive the written authorization of the head of their office before engaging in activities covered by Paragraphs (a)(2) and (b) of this section. The head of the employee's office before making his decision shall consult with the counselor or deputy counselor before making his decision.

42 FR 38893

(g) Bona fide reimbursements for expenses of travel and such other necessary subsistence may be accepted if (1) It is not prohibited by paragraph (a) of this section, (2) if reimbursement from the government is not received; and (3) it is not proscribed by Decision B-128527 of the Comptroller General dated March 7, 1967, or otherwise prohibited by law. Questions concerning application of the Comptroller General's decision should be referred to the counselor. However, this paragraph does not allow an employee to be reimbursed, or payment to be made on his behalf, for excessive personal living expenses, gifts, entertainment, or other personal benefits.

(h) An employee is not precluded by this § 0.735-40 or § 0.735-42 from:

(1) Participation in the affairs of or acceptance of an award for a meritorious public contribution or achievement given by a charitable, religious, professional, social, fraternal, nonprofit educational, recreational, public service, or civic organization.

42 FR 38893

§ 0.735-41 Misuse of information.

For the purpose of furthering a private interest, an employee shall not, except as provided in § 0.735-40(d), directly or indirectly use, or allow the use of, official information obtained through or in connection with his Government employment which has not been made available to the general public. See also section 68a of the Atomic Energy Act of 1954, 42 U.S.C., section 2098(a), "Public and acquired lands," which provides as follows:

a. No individual, corporation, partnership, or association, which had any part, directly or indirectly, in the development of the atomic energy program, may benefit by any location, entry, or settlement upon the public domain made after such individual, corporation, partnership, or association took part in such project, if such individual, corporation, partnership, or association, by reason of having had such part in the development of the atomic energy program, acquired confidential official information as to the existence of deposits of uranium, thorium, or other materials in the specific lands upon which such location, entry, or settlement is made, and subsequent to August 30, 1954, made such location, entry, or settlement, or caused the same to be made for his, or its, or their benefit.

31 FR 4502

§ 0.735-42 Gifts, entertainment, and favors.

(a) Except as provided in paragraph (b) or (e) of this section, an employee should not solicit or accept, directly or indirectly, any gift, gratuity, favor, entertainment, loan, or any other thing of monetary value, from a person who:

50 FR 25697

(1) Has, or is seeking to obtain, contractual or other business or financial relations with NRC;

(2) Conducts operations or activities that are regulated by NRC or is an applicant for a license from NRC; or

(3) Has interests that may be substantially affected by the performance or nonperformance of his official duty.

(b) The following exceptions are authorized as being necessary and appropriate in view of the nature of the NRC's work and the duties and responsibilities of its employees:

(1) When the circumstances make it clear that it is obvious family or personal relationships (such as those between the parents, children, or spouse of the employee and the employee) rather than the business of the persons concerned which are the motivating factors;

(2) Acceptance of food and refreshments of nominal value on infrequent occasions in the ordinary course of a luncheon or dinner meeting or other meeting or on an inspection tour where an employee may properly be in attendance;

(3) Acceptance of loans from banks or other financial institutions on customary terms to finance proper and usual activities of employees, such as home mortgage loans;

(4) Acceptance of unsolicited advertising or promotional material, such as pens, pencils, note pads, calendars and other items of nominal intrinsic value; and

(5) Acceptance of transportation not inconsistent with the provisions of paragraph (c) of this section.

(c) No employee shall accept free transportation in motor vehicles, aircraft, or other means, for official or unofficial purposes from NRC contractors, prospective contractors, licensees or prospective licensees, or representatives of any of them when such transportation might reasonably be interpreted as seeking to influence the impartiality of the employee or the agency.

31 FR 4502

(d) An employee shall not solicit a contribution from another employee for a gift to an official superior, make a donation to an official superior, or accept a gift from an employee receiving less pay than himself (5 U.S.C. 7351), nor shall an employee directly or indirectly solicit from, accept from, offer to, or grant to an official superior or subordinate employee a loan of more than a nominal amount. However, this paragraph does not prohibit (1) a voluntary gift of nominal value or donation in a nominal amount made on a special occasion such as marriage, illness, or retirement, or (2) a loan as described above of more than a nominal amount where a special personal or business relationship is involved, with prior approval of the higher-ranking employee's supervisor, after consultation with the counselor for NRC, or a deputy counselor, as provided in § 0.735-3(h). A copy of such approval shall be filed as provided for in § 0.735-28(e)(11).

38 FR 1271

(e) An employee shall not accept a gift, present, decoration, or other thing from a foreign government unless authorized by Congress as provided by the Constitution and in Public Law 95-105, 91 Stat. 862.

43 FR 1929

§ 0.735-43 Use of Government property.

An employee shall not directly or indirectly use, or allow the use of, Government property of any kind, including property leased to the Government, for other than officially approved activities. An employee has a positive duty to protect and conserve Government property, including equipment, supplies, and other property entrusted or issued to him.

§ 0.735-44 Scandalous conduct.

No employee shall engage in criminal, infamous, dishonest, immoral, or notoriously disgraceful conduct or other conduct prejudicial to the Government.

31 FR 4502

§ 0.735-45 Employee indebtedness.

Except as provided in § 0.735-42(d), the NRC considers the credit affairs of its employees essentially their own concern. However, employees are expected to conduct their credit affairs in a manner which does not reflect adversely on the Government as their employer. The NRC will not be placed in the position of acting as a collection agency for private debts or of determining the validity or amount of contested debts to private concerns. An employee is expected to pay each just financial obligation in a proper and timely manner, especially one imposed by law such as Federal, State, or local taxes. Failure on the part of an employee without good reason to honor just financial obligations or to make or adhere to satisfactory arrangements for settlement may be cause for disciplinary action. For the purpose of this section, a "just financial obligation" means one acknowledged by the employee or reduced to judgment by a court, and "in a proper and timely manner" means in a manner which NRC determines does not, under the circumstances, reflect adversely on the Government as the individual's employer.

46 FR 51715

§ 0.735-46 Gambling, betting, and lotteries.

An employee shall not participate, while on Government-owned or -leased property or while on duty for the Government, in any gambling activity including the operation of a gambling device, in conducting a lottery or pool, in a game for money or property, or in selling or purchasing a numbers slip or ticket. However, this section does not preclude activities:

(a) Necessitated by an employee's law enforcement duties; or

(b) Under section 3 of Executive Order 10927 and similar agency-approved activities.

§ 0.735-47 Handling of funds entrusted by fellow employees.

No employee shall receive, retain, or disburse funds entrusted to him by fellow employees, e.g., credit union deposits or donations to charitable organizations, except with the utmost care in the safeguarding of such funds and the maintenance of full and complete records with regard to the receipt, custody, and disbursement of such funds. Such records shall be made available to appropriate authorities upon proper request.

31 FR 4502

§ 0.735-48 Ex parte contacts.

Certain ex parte contacts by an employee are prohibited in quasi-judicial proceeding under §§ 2.719 and 2.780 of this chapter.

§ 0.735-49 Employment of persons on extended leave of absence from a previous employer with reemployment rights or other benefits with the previous employer.

(a) NRC may employ persons on extended leave of absence from private employers where it is the way most advantageous to the NRC to obtain qualified employees with needed skills and no violation of conflict of interest statutes would be involved. The necessity for continued employment of such persons shall be reviewed annually by the Director, Office of Administration. In their NRC assignments, such employees shall not be permitted to handle, directly or indirectly, or have access to, business confidential data of their former employers' competitors.

(b) When it is proposed to employ such a person, a statement of the exact terms and conditions of the leave of absence from his employer will be obtained from the prospective employee and submitted to the General Counsel for a prior determination of possible violation of statute.

(c) The following quotation from 18 U.S.C. 209 is pertinent to this situation.

(b) Nothing herein prevents an officer or employee of the executive branch of the U.S. Government or of any independent agency of the United States, or of the District of Columbia, from continuing to participate in a bona fide pension, retirement, group life, health or accident insurance, profit-sharing, stock bonus, or other employee welfare or benefit plan maintained by a former employer.

31 FR 4502

§ 0.735-49a Other proscribed actions.

An employee shall avoid any action, whether or not specifically prohibited by this Part 0, which might result in, or create the appearance of:

(a) Using a public office for private gain;

(b) Giving preferential treatment to any person;

(c) Impeding Government efficiency or economy;

(d) Losing complete independence or impartiality;

(e) Making a Government decision outside official channels; or

(f) Affecting adversely the confidence of the public in the integrity of the Government.

32 FR 13650

Subpart E—Ethical and Other Conduct and Responsibilities of Special Government Employees

§ 0.735-50 Use of Government employment.

A special Government employee shall not use his Government employment for a purpose that is, or gives the appearance of being, motivated by the desire for private gain for himself or another person, particularly one with whom he has family, business, or financial ties.

§ 0.735-51 Use of inside information.

(a) A special Government employee shall not use inside information obtained as a result of his Government employment for private gain for himself or another person either by direct action on his part or by counsel, recommendation, or suggestion to another person, particularly one with whom he has family, business, or financial ties. For the purpose of this section, "inside information" means information obtained under Government authority which has not become part of the body of public information.

(b) Special Government employees may teach, lecture, or write in a manner not inconsistent with § 0.735-40(d), in regard to employees.

§ 0.735-52 Coercion.

A special Government employee shall not use his Government employment to coerce, or give the appearance of coercing, a person to provide financial benefit to himself or another person, particularly one with whom he has family, business, or financial ties.

31 FR 4502

§ 0.735-53 Gifts, entertainment, and favors.

(a) Except as provided in paragraph (b) of this section, a special Government employee, while so employed or in connection with his employment, shall not receive or solicit from a person having business with NRC anything of value as a gift, gratuity, loan, entertainment, or favor for himself or another person, particularly one with whom he has family, business, or financial ties.

(b) Exceptions authorized for employees under § 0.735-42 shall have equal application with respect to special Government employees.

§ 0.735-54 Miscellaneous statutory provisions.

Each special Government employee shall acquaint himself with each statute that relates to his ethical and other conduct as a special Government employee of NRC and of the Government. The NRC official responsible for his appointment shall call his attention specifically to §§ 0.735-21, 0.735-22, 0.735-23, 0.735-24(c), 0.735-25, 0.735-26, 0.735-27, and 0.735-30.

§ 0.735-55 Applicable standards of conduct.

Special Government employees shall adhere to the standards of conduct made applicable to such employees by Subpart B of this part and to the standards of conduct made applicable to regular employees by §§ 0.735-43, 0.735-44, 0.735-46, and 0.735-48. In addition, special Government employees who are not consultants or advisers shall also be subject to §§ 0.735-45 and 0.735-47.

31 FR 4502

Annex A—Code of Ethics for Government Service (5 U.S.C. 7301)

Any person in Government service should:

1. Put loyalty to the highest moral principles and to country above loyalty to persons, party, or Government department.

2. Uphold the Constitution, laws, and legal Regulations of the United States and of all governments therein and never be a party to their evasion.

3. Give a full day's labor for a full day's pay; giving to the performance of his duties his earnest effort and best thought.

4. Seek to find and employ more efficient and economical ways of getting tasks accomplished.

5. Never discriminate unfairly by the dispensing of special favors or privileges to anyone, whether for remuneration or not; and never accept, for himself or his family, favors or benefits under circumstances which might be construed by reasonable persons as influencing the performance of his governmental duties.

6. Make no private promises of any kind binding upon the duties of office, since a Government employee has no private word which can be binding on public duty.

7. Engage in no business with the Government, either directly or indirectly, which is inconsistent with the conscientious performance of his governmental duties.

8. Never use any information coming to him confidentially in the performance of governmental duties as a means for making private profit.

9. Expose corruption wherever discovered.

10. Uphold these principles, ever conscious that public office is a public trust.

46 FR 51715

UNITED STATES NUCLEAR REGULATORY COMMISSION

RULES and REGULATIONS

TITLE 10, CHAPTER 1, CODE OF FEDERAL REGULATIONS—ENERGY

PART 0

CONDUCT OF EMPLOYEES

STATEMENTS OF CONSIDERATION

31 FR 4502
Published 3/17/66
Effective 3/17/66

Pursuant to and in accordance with sections 201 through 209 of Title 18 of the United States Code, Executive Order 11222 of May 8, 1965 (30 F.R. 6469), and Title 5, Chapter I, Part 735 of the Code of Federal Regulations, Part 0 is added to Title 10 of the Code of Federal Regulations, reading as set forth below. This Part 0 supersedes § 1.256 of this chapter.

This Part 0 has been approved by the Civil Service Commission under date of January 24, 1966.

32 FR 13650
Published 9/29/67
Effective 9/29/67

Miscellaneous Amendments

Part 0 is amended as follows:

Section 0.735–24(d) is amended to make reference to chapter 41 of title 5, United States Code, pertaining to acceptance of contributions, awards, or other expenses for training; § 0.735–28(a), Annex B and Annex C are amended to restrict the requirement relative to reporting employment and financial interests to those employees in positions in which the possibility of conflicts-of-interest is clear; § 0.735–28(c) is amended to provide that for Headquarters employees their respective reviewing officials instead of the Assistant General Manager for Administration shall notify employees of the requirement for submitting statements; § 0.735–28(d) (4) and (5) are amended to exclude the reporting of remote and inconsequential interests and, for regular Government employees, to eliminate quarterly supplementary statements; § 0.735–28(f) is amended to insure the confidentiality of statements submitted; § 0.735–28(h) is amended to add the positions of the Chairman, Atomic Safety and Licensing Board Panel and Director, Office of Safeguards and Materials Management, to those positions reporting to the Commission and the General Manager, respectively, to conform to organizational changes; § 0.735–28(i) is added to evidence the availability of an agency's grievance procedure for review of a complaint by an employee concerning the applicability of the reporting requirement; § 0.735–30 is amended to correct statutory references made obsolete by the codification of title 5, United States Code; § 0.735–40(e) is amended to make reference to section 4111 of title 5, United States Code; § 0.735–40(g) is amended to show that its provisions do not apply to non-Government reimbursement when proscribed by Decision B–128527 of the Comptroller General dated March 7, 1967; § 0.735–42(d) is amended to indicate the circumstances under which a gift to an official superior may be allowed; § 0.735–42(e) is added to include reference to Public Law 89–673, 80 Stat. 952, authorizing the acceptance of souvenirs from a foreign government under certain circumstances; and § 0.735–49a is transferred from former § 0.735–42(d). These amendments to Part 0 were approved by the Civil Service Commission on September 19, 1967, and are effective upon publication in the FEDERAL REGISTER.

38 FR 1271
Published 1/11/73
Effective 1/11/73

Solicitations and Indebtedness

The Atomic Energy Commission is amending Part 0 of its regulations concerning the credit affairs of its employees.

Because these amendments relate to a matter of agency management and personnel, notice of proposed rule making and public procedure thereon are unnecessary. These amendments are effective on January 11, 1973.

40 FR 8774
Published 3/3/75
Effective 3/3/75

Energy Reorganization Act; Revision to Chapter I to Reflect Organizational and Procedural Changes

See Part 2 Statements of Consideration

40 FR 50703
Published 10/31/75
Effective 10/31/75

Clarifying and Corrective Amendments to Chapter

See Part 30 Statements of Consideration.

42 FR 20138
Published 4/18/77
Effective 4/18/77

42 FR 20138
Published 4/18/77
Effective 4/18/77

Corrective and Minor Amendments to Chapter

AGENCY: Nuclear Regulatory Commission.

ACTION: Final Rule.

SUMMARY: This rule makes corrective and minor amendments to the Commission's regulations "Conduct of Employees," "Standards for Protection Against Radiation," and "Licensing of Production and Utilization Facilities."

EFFECTIVE DATE: April 18, 1977

FOR FURTHER INFORMATION CONTACT:

Gerald L. Hutton, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, D.C., 301–492–7211.

SUPPLEMENTARY INFORMATION: Notice is hereby given of the amendment of the Nuclear Regulatory Commission's regulations 10 CFR Parts 0, 20 and 50.

The amendment of Part 0 makes a minor correction in § 0.735–3(h), correcting the reference therein to "The Solicitor" to read "The General Counsel."

The amendments of Part 20 amend § 20.405(a), Reports of overexposures and excessive levels and concentrations, to provide that such reports shall be made to the Director of the appropriate NRC Regional Office listed in Appendix D of Part 20 with a copy to the Director of Inspection and Enforcement.

The amendments of Part 20 also correct a printing error in footnote 3 to § 20.103(a). "Multiple" is corrected to read "Multiply".

In paragraph 2. of Appendix F, 10 CFR Part 50, the sentence "NRC will take title to the radioactive waste material upon transfer to a Federal Repository". is corrected to read "The Energy Research and Development Administration will take title to the radioactive waste material upon transfer to a Federal Repository.". At the time of implementation of the Energy Reorganization Act of 1974, the above referenced sentence was amended as part of an overall revision of the regulations changing references to "AEC" to read "NRC". In the case of this sentence, however, the reference to AEC should have been changed to the Energy Research and Development Administration as the cognizant Federal Agency.

The amendment of § 50.59(a)(2)(i) corrects the words "accident of malfunction of equipment" to read "accident or malfunction of equipment". The amendment to footnote 2 of Appendix I, 10 CFR Part 50 changes the reference to "Section 50.36a(2)" to read "Section 50.36a(a)(2)."

Because these amendments relate solely to corrections and minor amendments, the Commission has found that good cause exists for omitting notice of proposed rule making, and public procedure thereon, as unnecessary, and for making the amendments effective upon publication in the FEDERAL REGISTER.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Parts 0, 20 and 50, are published as a document subject to codification.

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42 FR 38893
Published 8/1/77
Effective 9/12/77

PART 0—CONDUCT OF EMPLOYEES

Outside Employment and Other Activity

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations pertaining to the "Conduct of Employee." Since it is often difficult for NRC employees to determine what constitutes a conflict of interest with respect to outside employment or other activities, the Commission deemed it appropriate to specify these proscriptions in greater detail as set forth in the amendments which follow.

EFFECTIVE DATE: September 12, 1977.

FOR FURTHER INFORMATION CONTACT:

Trip Rothschild, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. (301–634–1465).

SUPPLEMENTARY INFORMATION: The Nuclear Regulatory Commission gives notice herewith that it has amended 10 CFR 0.735–40. NRC regulations presently prohibit NRC employees from engaging in any employment or outside activity which is not compatible with the full and proper discharge of the duties and responsibilities of his Government employment. Since it is often difficult for employees to determine what constitutes a conflict of interest with respect to outside employment or other activities, the Commission deemed it appropriate to specify these proscriptions in greater detail as set forth in the amendments which follow.

Because these amendments relate solely to matters of agency management of personnel, good cause exists for omitting notice of proposed rule making, and public procedure thereon.

Pursuant to section 2201(p) of Title 42 of the United States Code, Executive Order 11222 of May 8, 1965, 5 CFR 735–104, and sections 552 and 553 of Title 5 of the United States Code, the following amendments of Title 10, Chapter I, Code of Federal Regulations, Part 0 are published as a document subject to codification.

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43 FR 1929
Published 1/13/78
Effective 1/1/78

PART 0—CONDUCT OF EMPLOYEES

Foreign Gifts and Decorations

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations so that they refer to the recently enacted amendments in Pub. L. 95-105 to the Foreign Gifts and Decorations Act of 1966.

EFFECTIVE DATE: January 1, 1978.

FOR FURTHER INFORMATION CONTACT:

William C. Parler, Office of the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone 301-492-7527.

SUPPLEMENTARY INFORMATION: Because this amendment merely updates a reference to a newly applicable law and relates solely to matters of agency management of personnel, good cause exists for omitting notice of proposed rulemaking, and public procedure thereon and for making the rule effective on January 1, 1978 without the customary 30 day waiting period.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, Pub. L. 95-105, 91 Stat. 862, and sections 552 and 553 of Title 5 of the United States Code, the following amendment to Title 10, Chapter 1, Code of Federal Regulations, Part 0 is published as a document subject to codification.

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44 FR 41422
Published 7/17/79
Effective 7/17/79

10 CFR Part 0

Conduct of Employees; Ownership of Stocks, Bonds, and Other Security Interests by NRC Employees

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission has revised its regulations governing the ownership of stocks, bonds, and other security interests by NRC employees.

EFFECTIVE DATE: July 17, 1979.

FOR FURTHER INFORMATION CONTACT: Trip Rothschild, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (202 634–1465).

SUPPLEMENTARY INFORMATION: The Nuclear Regulatory Commission has conducted a thorough review of its regulations governing the ownership of stocks, bonds, and other security interests by NRC employees and determined that several changes should be made to 10 CFR 0.735–21 and 0.735–29. NRC employees and the National Treasury Employees Union commented on these proposed changes and the final rule adopted by the Commission incorporates most of the comments.

The amendments to 10 CFR 0.735–29 are best understood by briefly summarizing the origin of that section. Added to Part 0 on December 19, 1973, § 0.735–29 prohibited Atomic Energy Commission (The Commission's predecessor agency) employees involved in licensing and regulatory activities from owning security interests in the following types of entities: (a) Any publicly or privately owned utility company engaged in the generation, distribution or sale of electric energy, or parent company of such company; (b) any company manufacturing or selling nuclear power or test reactors; (c) any architectural-engineering company primarily engaged in the design or construction of nuclear power or test reactor facilities; and (d) any company whose business consists substantially of serving as a consultant to companies engaged in activities licensed or regulated by the Commission. Upon creation of the Nuclear Regulatory Commission (which acceded to the Atomic Energy Commission's regulatory authority), the decision was made to apply the prohibition of § 0.735–29 to all full-time NRC employees as well as to certain special government employees.

The Commission is amending § 0.735–29 to better reflect the Commission's regulatory responsibilities and an individual employee's role within the agency. NRC employees will for the first time be permitted to own stock, bonds or other security interests in electric utilities which have not been authorized by the Commission to construct or operate a nuclear reactor or do not have applications pending before the Commission seeking early site review or authorization to construct or operate a nuclear reactor. The Commission does not have jurisdiction over non-nuclear electric utilities and accordingly, we find little justification for prohibiting NRC employees from owning stock in those companies. Of course, once a utility files an application seeking early site review or authorization to construct a nuclear reactor, employees would be prohibited from owning securities issued by that company and employees would be required to divest themselves of any security interests held in that company. The Commission will continue to prohibit its employees from owning bonds issued by state and local governmental entities in those cases where the primary purpose of the bond is to raise funds to operate or constuct a nuclear reactor. The Commission is also retaining its prohibition on security interests issued by companies manufacturing or selling nuclear power or test reactors. The Commission is revising its prohibition on architectural-engineering companies so that it will be easier to provide employees with a list of firms whose securities they may not own. Commission employees will be prohibited from owning securities issued by architectural-engineering companies that have been engaged to provide services relating to a nuclear facility by an applicant for a construction permit, a holder of a construction permit, or an applicant for an operating license. In addition, employees will be prohibited from owning securities issued by architectural-engineering companies which have filed a standard reference design that is under Commission review, or has been approved by the Commission and is currently effective.

The Commission will also for the first time prohibit its employees from owning securities issued by fuel cycle applicants or licensees (companies engaged in milling, converting, fabricating, reprocessing, storing, or disposing of source or special nuclear material). This category is added because a large number of Commission employees are involved in regulatory activities related to the nuclear fuel cycle.

The Commission is deleting the bar against owning securities issued by companies whose business consists substantially of serving as consultants to companies engaged in NRC regulated activities. Most of the consulting firms are partnerships or small corporations which do not issue public securities, and therefore the prohibition had little effect. Furthermore, it was impossible to provide employees with a list of the companies covered by the prohibition because the Commission was unable to define what constituted "substantially" serving as a consultant to companies engaged in NRC regulated activities.

The foregoing security ownership prohibitions will be applicable to all NRC employees occupying positions at the GS–13 level or above, and as well as all other employees who provide input into the decision-making process. (These employees will be designated by the Commission according to their occupational code.) The security ownership prohibitions will apply to the NRC employee, and to the employee's spouse, minor children, and any other member of the employee's household. The Commission considered applying the prohibitions as is done presently to all Commission employees. The Commission decided not to do so because many employees, such as clerical personnel, do not participate in the decision-making process. A far-ranging restriction on their personal investing freedom is unnecessary. This, however, does not create a regulatory gap which could allow these employees to profit from inside information gained as an NRC employee. NRC regulations prohibit all employees from directly or indirectly using or allowing the use of official information, obtained through or in connection with their government employment, which has not been made available to the general public, to further a private interest. 10 CFR 0.735–41.

To implement these provisions, NRC employees subject to this restriction will be given a list twice a year of those securities which they are prohibited from purchasing. Employees will be given 365 days from the time the list is published to divest themselves of any prohibited security interest. Employees will not be permitted to work on matters affecting an entity until they have divested themselves of the prohibited security, notwithstanding the provision of § 0.735–21(c), discussed below. Employees will for the first time be required to certify annually that they are in compliance with § 0.735–29. Employees will also sign such a certification within thirty days after commencing NRC employment. This codifies existing NRC practice.

With respect to securities which NRC employees are not prohibited from owning, § 0.735–21 of the Commission's regulations permits NRC employees, including special government employees, to work on matters affecting the issuing entity provided that the current market value of the security interests held by the employee and members of his immediate household do not exceed $7,500. The Commission is reducing that $7,500 figure to $1,000. The Commission believes that in some cases $7,500 may be a significant portion of an employee's liquid assets and that an investment of that size could conceivably affect an employee's judgment. Accordingly, we are reducing the *de minimis* figure.

Commissioner Bradford does not concur in several of the amendments adopted by the Commission. He believes that the security ownership prohibition should be applied to all NRC employees. He would extend the security ownership prohibition to all electric utilities and to the major consulting firms which the Commission would designate. Finally, he believes that employees should not be permitted to work on matters affecting an entity in which they or members of their household have a financial interest, regardless of the amount.

Because these amendments relate solely to matters of agency management or personnel, good cause exists for omitting notice of proposed rulemaking, and public procedure thereon, as unnecessary, and for making the amendments effective July 17, 1979.

Pursuant to section 2201(p) of Title 42 of the United States Code, Executive Order 11222 of May 8, 1965, 5 CFR 735.104, and sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 0, are published as a document subject to codification, to be effective July 17, 1979.

44 FR 62880
Published 11/1/79
Effective 11/1/79

10 CFR Part 0

Change for Office for Reporting Complaints of Misconduct

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is changing the office to which complaints of fraud, graft, corruption, diversion of NRC assets, and misconduct of NRC employees are reported, from the Office of Administration to the Office of Inspector and Auditor. In addition, references to the "Office of the Agency Inspector and Auditor" and to the "Agency Inspector and Auditor" are changed to reflect the correct title for each.

EFFECTIVE DATE: November 1, 1979.

FOR FURTHER INFORMATION CONTACT: J. M. Felton, Director, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: 301–492–7211.

SUPPLEMENTARY INFORMATION: The amendment eliminates the inconsistency between 10 CFR 0.735–3(d)(2) and 0.735–3(g) in that the former required that complaints of fraud, graft, corruption, diversion of NRC assets, and misconduct of NRC employees to be reported to the Office of Administration while the latter required that investigations of such deeds be carried out by the Office of the Agency Inspector and Auditor (now called Office of Inspector and Auditor). Accordingly, in 10 CFR 0.735–3(d)(2), the title "Office of Administration" is deleted, and inserted in its place is the title "Office of Inspector and Auditor." In addition, references to the "Office of the Agency Inspector and Auditor" and to the "Agency Inspector and Auditor" are changed to the correct title for each.

Since these amendments relate solely to minor procedural matters, notice of proposed rule making and public procedure thereon are unnecessary and good cause exists to make the amendments effective upon publication in the Federal Register.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 0 are published as a document subject to codification.

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45 FR 26022
Published 4/17/80
Effective 4/17/80

10 CFR Part 0

Filing of Confidential Statements of Employment and Financial Interests by NRC Employees

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission has revised its regulations regarding those NRC employees who are required to fill out confidential statements of employment and financial interests and the dates when these statements are due.

EFFECTIVE DATE: April 17, 1980.

FOR FURTHER INFORMATION CONTACT: Trip Rothschild, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (202–634–1465).

SUPPLEMENTARY INFORMATION: The Nuclear Regulatory Commission has revised its regulations to provide that a NRC employees classified at grades GG–13 through GG–15 will file confidential statements of employment within thirty days after commencing NRC employment, and shall file annual statements thereafter which will be due on May 15. All attorneys in the Offices of the General Counsel and Executive Legal Director, all professionals in the Office of Policy Evaluation, and all contracting officers in the Office of Administration will be covered by the reporting requirement, even if they are paid at a rate below GG–13. Previously, most but not all NRC employees grades GG–13 through GG–15 were subject to the reporting requirement. The statements were due on July 10.

Because these amendments relate solely to matters of agency management or personnel, good cause exists for omitting notice of proposed rulemaking, and public procedure thereon, as unnecessary, and for making the amendments effective April 17, 1980.

Pursuant to Executive Order 11222 of May 8, 1965, 5 CFR 735.104, and sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 0, are published as a document subject to codification, to be effective April 17, 1980.

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46 FR 51715
Published 10/22/81
Effective 10/22/81

10 CFR Part 0

Conduct of Employees; Post-Employment Restrictions

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations on the conduct of employees in order to bring the section placing post-employment restrictions on former NRC employees into conformity with the post-employment restrictions of the Ethics in Government Act of 1978, as amended. It has also adopted several other minor amendments and nomenclature changes to its regulations on the conduct of employees.

EFFECTIVE DATE: October 22, 1981.

FOR FURTHER INFORMATION CONTACT: Trip Rothschild, Esq., Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (202–634–1465).

SUPPLEMENTARY INFORMATION: The Ethics in Government Act of 1978 imposed new post-employment restrictions on agency personnel. The present regulations, 10 CFR 0.735–26, are based on 1962 legislation which has been superseded by that Act. The changes will bring NRC's regulations into conformity with the Ethics in Government Act. In addition, the Commission has adopted several minor amendments and nomenclature changes to 10 CFR Part 0.

Because the amendments involve matters relating to agency management and personnel, good cause exists for omitting notice of proposed rulemaking, and public procedure thereon, as unnecessary and for making the rules effective upon October 22, 1981.

Paperwork Reduction Act Statement

The provisions of the Paperwork Reduction Act of 1980, Pub. L. 96–511, 94 Stat. 2812, are not applicable to this final rule because the final rule does not contain any new or amended requirements for recordkeeping, reporting, plans or procedures, applications, or any other type of information collection.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of Title 5 of the United States Code, notice is hereby given that the following amendments to 10 CFR Part 0 are published as a document subject to codification.

49 FR 19623
Published 5/9/84
Effective 5/9/84

10 CFR Parts 0, 4, 9, 11, 19, 20, 21, 25, 30, 31, 32, 33, 34, 35, 40, 50, 51, 55, 70, 71, 73, 75, 95, 100, 110, 140, and 150

Information Collection Requirements; Display of OMB Control Numbers

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations to indicate the Office of Management and Budget (OMB) control numbers under which the information collection requirements imposed by the regulations have been approved by OMB. This action is necessary to comply with OMB regulations implementing the Paperwork Reduction Act.

EFFECTIVE DATE: May 9, 1984.

FOR FURTHER INFORMATION CONTACT: Brenda Shelton, Acting Chief, Document Management Branch, Division of Technical Information and Document Control, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Telephone (301) 492–8132.

SUPPLEMENTARY INFORMATION: The Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.) establishes the policies and procedures for controlling paperwork burdens imposed by Federal agencies on the public.

The Act requires that each agency obtain Office of Management and Budget (OMB) review and clearance of the information collection requirements it imposes on the public. The Act also authorizes OMB to issue the regulations necessary to carry out its authority under the Act. These regulations (5 CFR Part 1320) were published in the **Federal Register** in final form on March 31, 1983 (48 FR 13666).

The Nuclear Regulatory Commission is issuing this regulation to comply with 5 CFR 1320.7(f)(2). That provision requires agencies to ensure that the OMB control numbers, under which the information collection requirements contained in its regulations are approved by OMB, appear in the Code of Federal Regulations. The NRC is including a section in each part of 10 CFR Chapter I that contains an information collection requirement approved by OMB as of December 31, 1983. This section sets out the OMB control number under which the information collection requirements in that part are approved and lists the sections within the part that contain approved information collection requirements. The NRC is also amending sections of the regulations that contain information collection requirements involving the use of an approved form to identify the form by number.

Because this is a nonsubstantive amendment dealing with procedural matters and agency management, the notice provisions of the Administrative Procedure Act (5 U.S.C. 553) do not apply. Opportunity for public comment is unnecessary because this is a minor procedural amendment in which the public is unlikely to have an interest. The amendment is effective upon publication in the **Federal Register** without a 30 day delay because this is an amendment dealing with agency management that is necessary to comply with the regulations issued by OMB. This amendment does not impose a burden, penalty, or obligation on any person or organization.

List of subjects in 10 CFR Parts 0, 4, 9, 11, 19, 20, 21, 25, 30, 31, 32, 33, 34, 35, 40, 50, 51, 55, 70, 71, 73, 75, 95, 100, 110, 140, and 150

Reporting and recordkeeping requirements.

Under the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552, the following amendments to 10 CFR Chapter I are published as a document subject to codification.

The authority citation for this document is:

(Sec. 161, Pub. L. 83–703, 68 Stat. 948, as amended (42 U.S.C. 2201); sec. 201, Pub. L. 93–438, 88 Stat. 1242, as amended (42 U.S.C. 5841); Pub. L. 96–511, 94 Stat. 2812 (44 U.S.C. 3501 et seq.))

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49 FR 21699
Published 5/23/84

10 CFR Parts 21, 30, 31, 40, and 70

Information Collection Requirements, Display of OMB Control Numbers

Correction

In FR Doc. 84–12516 beginning on page 19623 in the issue of Wednesday, May 9, 1984, make the following corrections:

1. On page 19624, third column, the caption reading "§ "21.61 [Removed]" should have read "§ 21.61 [Amended]".

2. On page 19625, first column, amendatory paragraph 15, "In § 30.17" should have read "In § 30.37".

3. In the middle column of page 19625, in § 31.4(a), fourth line, "in this part or the Office of" should have read "in this part to the Office of". In the eighth line of the same paragraph, "OMB approved" should have read "OMB has approved".

4. On page 19626, third column, § 40.31, paragraph (g), in the thirteenth line, remove the parenthesis after "Form N–71" and insert a period.

5. On page 19628, § 70.21, paragraph (g), in the eighth line from the top of the middle column of the page, "74.14" should have read "75.14".

➤ 50 FR 25697
Published 6/21/85
Effective 6/21/85
Extended comment period 7/22/85.

10 CFR Part 0

Conduct of Employees; Minor Amendments

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its standards of conduct to codify in NRC's regulations provisions of the Ethics in Government Act of 1978 (18 U.S.C. 207) as amended, relating to reporting of financial assets by senior NRC officials. The Commission is also adopting several other amendments to its regulations on employee conduct. The amendments will exempt former NRC employees from the post-employment restrictions of 18 U.S.C. 207 in order to communicate scientific or technological information to the NRC; eliminate an ambiguity relating to the acceptance by NRC employees of gifts, meals, and entertainment from foreign governments; and modify the regulations to require only annual publication of the prohibited security interests list (formerly published twice annually).

EFFECTIVE DATE: June 21, 1985. However, the Commission is extending the opportunity for public comment on this final rule until July 22, 1985.

ADDRESSES: Written comments should be submitted to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch.

FOR FURTHER INFORMATION CONTACT: Trip Rothschild, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Telephone: 202–634–1465.

SUPPLEMENTARY INFORMATION: Since 1979, senior NRC officials have submitted Financial Disclosure Reports (Standard Form 278) in accordance with the provisions of the Ethics in Government Act of 1978. This reporting requirement currently is not codified in the Commission's regulations. The amendments add a new section 10 CFR 0.735–28a to the regulations, stating that employees paid at a salary rate of GG-16 and above or holding positions that are excepted from the regular competitive appointment process by reason of being of a confidential or policymaking character must file financial disclosure reports that will be made available to the public. The Commission has decided not to incorporate into its regulations the detailed regulations regarding the financial reporting requirements under the Ethics in Government Act. Instead, a cross reference is made to the detailed regulations promulgated by the Office of Government Ethics that can be found in 5 CFR Part 734.

Under § 0.735–29(a), most NRC professional employees are barred from owning stocks, bonds, and other security interests issued by the major companies in the commercial nuclear field. Section 0.735–29(b) currently provides that the Commission will publish a list of the prohibited security interests twice a year. Because there have been few changes in the list from year to year, the Commission has determined that it is not necessary to revise the list twice a year. Accordingly, it is modifying its regulations to require only annual publication of the list.

The Commission is also adopting an amendment to eliminate an ambiguity in § 0.735–42 relating to the acceptance by NRC employees of gifts, meals, and entertainment from foreign governments. The amendment makes clear that employees may accept gifts, meals and entertainment from foreign governments when acceptance is not barred by the Foreign Gifts and Decorations Act (Pub. L. 95–105).

Finally, the agency is promulgating procedures pursuant to section 207(f) of the Ethics in Government Act that would permit former NRC employees to be exempted from the post-employment restrictions of 18 U.S.C. 207 in order to communicate scientific or technological information to the NRC.

Because these amendments relate solely to matters of agency management or personnel, good cause exists for omitting notice of proposed rulemaking and public procedure thereon, as unnecessary, and for making the amendments effective upon publication in the **Federal Register**.

Environmental Impact: Categorical Exclusion

The NRC has determined that this final rule is the type of action described in categorical exclusion 10 CFR 51.22(c)(1). Therefore neither an environmental impact statement nor an environmental assessment has been prepared for this final rule.

Paperwork Reduction Act Statement

This final rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501, *et seq.*). Existing requirements were approved by the Office of Management and Budget approval number 3206–0092.

List of Subjects in 10 CFR Part 0

Conflict of interest, Penalty.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is adopting the following amendments to 10 CFR Part 0.

PART 1

STATEMENT OF ORGANIZATION AND GENERAL INFORMATION

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Sec.
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1.2 Sources of additional information.
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1.10 The Commission.

PANELS, BOARDS, AND COMMITTEES

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1.21 Other committees, boards and panels.

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1.80 Description and custody of NRC seal.
1.81 Use of NRC seal or replicas.
1.82 Establishment of official NRC flag.
1.83 Use of NRC flag.
1.84 Report of violations.

Authority: Secs. 23, 161, 68 Stat. 925, 948, as amended (42 U.S.C. 2033, 2201); sec. 29, Pub. L. 85–256, 71 Stat. 579, Pub. L. 95–209, 91 Stat. 1483 (42 U.S.C. 2039); sec. 191, Pub. L. 87–615, 76 Stat. 409 (42 U.S.C. 2241); secs. 201, 203, 204, 205, 209, 88 Stat. 1242, 1244, 1245, 1246, 1248, as amended (42 U.S.C. 5841, 5843, 5844, 5845, 5849); 5 U.S.C. 552, 553; Reorganizations Plan No. 1 of 1980, 45 FR 40561, June 16, 1980.

Sec. 1.40(q) also issued under secs. 132, 135, 96 Stat. 2230, 2232 (42 U.S.C. 10152, 10155). 50 FR 5548

Subpart A—Introduction

§ 1.1 Creation and authority.

(a) The Nuclear Regulatory Commission was established by the Energy Reorganization Act of 1974, as amended, Pub. L. 93–438, 88 Stat. 1233 (42 U.S.C. 5801 et seq.). This Act abolished the Atomic Energy Commission and, by section 201, transferred to the Nuclear Regulatory Commission all the licensing and related regulatory functions assigned to the Atomic Energy Commission by the Atomic Energy Act of 1954, as amended, Pub. L. 83–703, 68 Stat. 919 (42 U.S.C. 2011 et seq.). These functions included those of the Atomic Safety and Licensing Board Panel and the Atomic Safety and Licensing Appeal Panel. The Energy Reorganization Act became effective January 19, 1975 (E.O. 11834).

(b) As used in this part, "Commission" means the five members of the Nuclear Regulatory Commission or a quorum thereof sitting as a body, as provided by section 201 of the Energy Reorganization Act of 1974, as amended. "NRC" means the Nuclear Regulatory Commission, the agency established by Title II of the Energy Reorganization Act of 1974, as amended, comprising the members of the Commission and all offices, employees, and representatives authorized to act in any case or matter. 42 FR 36797

§ 1.2 Sources of additional information.

(a) The definitive statement of the NRC's organization, policies, procedures, assignments of responsibility, and delegations of authority is in the Nuclear Regulatory Commission Manual and other elements of the NRC's Management Directives System, including local directives issued by Regional Offices. Copies of the Manual, other elements of the Management Directives System, and agency operating procedures that affect the public are available for public inspection and copying at the NRC Public Document Room, 1717 H Street NW., Washington, D.C. and at each of NRC's Regional Offices. Information may also be obtained from the Office of Public Affairs or from Public Affairs Officers at the Regional Offices.

(b) Commission meetings are open to the public, as provided by the Government in the Sunshine Act, unless they fall within an exemption to the Act's openness requirement and the Commission also has determined that the public interest requires that those particular meetings be closed. Information concerning Commission meetings may be obtained from the Office of the Secretary.

(c) Information regarding the availability of NRC records under the Freedom of Information Act and the Privacy Act of 1974 may be obtained from the Division of Rules and Records, Office of Administration. NRC's regulations are published in the FEDERAL REGISTER and codified in Title 10 of the Code of Federal Regulations. They are also published in "NRC Rules and Regulations," available on a subscription basis from the Superintendent of Documents, U.S. Government Printing Office. Final opinions made in the adjudication of cases are published in "Nuclear Regulatory Commission Issuances," available on a subscription basis from the National Technical Information Service, Springfield, Va. 22161. 42 FR 36797

§ 1.3 Location of principal offices and regional offices.

(a) The principal NRC offices are located in the Washington, D.C. area. Facilities for the service of process and papers are maintained within the District of Columbia at 1717 H Street, NW. The mailing address for all NRC Headquarters offices is Washington, D.C. 20555. The locations of NRC offices in the Washington area are:

(1) Air Rights III Building, 4550 Montgomery Avenue, Bethesda, Maryland.

(2) East West/South Towers Building, 4340 East West Highway, Bethesda, Maryland. 50 FR 21036

(3) East West/West Towers Building, 4350 East West Highway, Bethesda, Maryland.

(4) Maryland National Bank building, 7735 Old Georgetown Road, Bethesda, Maryland.

(5) Matomic Building, 1717 H Street, NW, Washington, D.C.

(6) Nicholson Lane Building, 5650 Nicholson Lane, Rockville, Maryland.

(7) Phillips Building, 7920 Norfolk Avenue, Bethesda, Maryland.

(8) Willste Building, 7915 Eastern Avenue, Silver Spring, Maryland.

(9) Woodmont Building, 8120 Woodmont Avenue, Bethesda, Maryland.

(b) The addresses of the NRC Regional Offices (see § 1.64) are:

Region I, USNRC, 631 Park Avenue, King of Prussia, PA 19406.
Region II, USNRC, 101 Marietta Street, NW. Suite 2900, Atlanta, GA 30323.
Region III, USNRC, 799 Roosevelt Road, Glen Ellyn, IL 60137.
Region IV, USNRC, 611 Ryan Plaza Drive, Suite 1000, Arlington, TX 76011.
USNRC, Region IV Uranium Recovery Field Office, 730 Simms Street, P.O. Box 25325, Denver, CO 80225.
Region V, USNRC, 1450 Maria Lane, Suite 210, Walnut Creek, CA 94596.

49 FR 47823

Subpart B—Headquarters

§ 1.10 The Commission.

(a) The Nuclear Regulatory Commission, composed of five members, one of whom is designated by the President as Chairman, is established pursuant to section 201 of the Energy Reorganization Act of 1974, as amended. The Chairman is the principal executive officer of the Commission, and exercises its executive and administrative functions with respect to appointment and supervision of personnel, except as otherwise provided by the Energy Reorganization Act of 1974, as amended; distribution of business; use and expenditure of funds (except that the function of revising budget estimates and purposes is reserved to the Commission); and appointment, subject to approval of the Commission, of heads of major administrative units under the Commission.

(b) The following staff units and officials report directly to the Commission: Atomic Safety and Licensing Board Panel, Atomic Safety and Licensing Appeal Panel, Office of Inspector and Auditor, Office of Policy Evaluation, Office of the General Counsel, Office of the Secretary, Office of Public Affairs, Office of Congressional Affairs, the Executive Director for Operations, and other committees and boards which are authorized or established specifically by the Act. The Directors of the Offices of Nuclear Reactor Regulation, Nuclear Material Safety and Safeguards, and Nuclear Regulatory Research may communicate with and report directly to the Commission, under the provisions of section 209 of the Energy Reorganization Act of 1974. The Advisory Committee on Reactor Safeguards also reports directly to the Commission.

42 FR 36797

§ 1.11 Atomic Safety and Licensing Board Panel.

The Atomic Safety and Licensing Board Panel is the organizational group from which Atomic Safety and Licensing Boards are selected. These three-member boards, named in accordance with the provisions of section 191 of the Atomic Energy Act, conduct such hearings as the Commission may authorize or direct, make such intermediate or final decisions as the Commission may authorize in proceedings to grant, suspend, revoke, or amend licenses or authorizations, and perform such other regulatory functions as the Commission may specify. The Panel develops procedures and makes recommendations to the Commission regarding activities of the hearing boards. The Panel shall be comprised of a Chief Administrative Judge who shall be Chairman and such other Administrative Judges as may be appointed members of the Panel.

§ 1.12 Atomic Safety and Licensing Appeal Panel.

The Atomic Safety and Licensing Appeal Panel is the organizational group from which Atomic Safety and Licensing Appeal Boards are selected. Under powers delegated by the Commission, these three-member Boards exercise the authority and perform the regulatory review functions which would otherwise be exercised and performed by the Commission. They perform these functions in proceedings on licenses under 10 CFR Part 50, and such other licensing proceedings as the Commission may specify, reviewing initial decisions and other issuances of Atomic Safety and Licensing Boards and other presiding officers. The Panel shall be comprised of a Chief Administrative Judge who shall be Chairman and such other Administrative Judges as may be appointed members of the Panel.

45 FR 80270

§ 1.20 Advisory Committee on Reactor Safeguards.

The Advisory Committee on Reactor Safeguards was established by Section 29 of the Atomic Energy Act of 1954, as amended, and transferred to the NRC pursuant to the Energy Reorganization Act of 1974, as amended. The Committee reviews safety studies, and applications for construction permits and operating licenses for production and utilization facilities, and makes reports thereon; advises the Commission with regard to the hazards of proposed or existing nuclear facilities and the adequacy of proposed reactor safety standards; and reviews matters specifically referred to it by the Commission, including generic issues and proposed amendments or changes to facility construction permits or operating licenses. Similarly, upon request from the Department of Energy (DOE) the Committee performs reviews, provides reports, and advises DOE with regard to the hazards of DOE nuclear activities and facilties. The Committee on its own initiative may conduct reviews of specific generic matters or nuclear facility safety-related items.

43 FR 30270

§ 1.21 Other committees, boards, and panels.

Pursuant to section 161a. of the Atomic Energy Act of 1954, as amended, the Commission may establish advisory bodies to make recommendations to it. Currently only one such committee is in existence.

(a) The Advisory Committee on Medical Use of Isotopes (ACMI) was established by the Atomic Energy Commission in July 1958. The ACMI, composed of physicians and scientists, considers medical questions referred to it by the NRC staff, and renders expert opinion regarding medical uses of byproduct material. The ACMI also advises the NRC staff, as requested, on matters of policy regarding licensing of the medical uses of byproduct material.

COMMISSION STAFF

§ 1.30 Office of Inspector and Auditor.

The Office of Inspector and Auditor: (a) develops policies and standards governing NRC's financial and management audit program; (b) plans and directs NRC's long-range comprehensive audit program; (c) conducts NRC's day-to-day internal audit activity; (d) conducts investigations and inspections to ascertain and verify the facts with regard to the integrity of all NRC operations; (e) investigates possible irregularities or alleged misconduct of NRC employees, equal employment opportunity and civil rights complaints, and claims for personal property loss or damage; (f) refers suspected or alleged criminal violations to the Department of Justice, after appropriately informing or consulting with the Office of General Counsel; except that in referrals requiring prompt field response (such as sabotage, terrorism, or theft of special nuclear material), the Office of Inspection and Enforcement shall make direct referral to the Federal Bureau of Investigation and thereafter coordinate with the Office of Inspector and Auditor; (g) under the Commission's "open door" policy, hears individual employee concerns regarding NRC operations and activities, and, as appropriate, investigates such concerns; (h) maintains liaison with the General Accounting Office and other audit organizations; (i) maintains liaison with the Department of Justice and other law enforcement agencies in criminal and other investigative matters; and (j) provides reports and recommendations to the Commission on the results of its audits, investigations, and inspections.

42 FR 36797

§ 1.31 Office of Policy Evaluation.

The Office of Policy Evaluation: (a) provides for the Commission an independent evaluation of program policy objectives; (b) reviews staff issue papers and policy recommendations to determine if they are complete, balanced, and consistent with Commission guidance; (c) provides independent technical evaluation of selected cases presented to the Commission for adjudication; (d) conducts analyses and studies as requested by the Commission or on a self-initiated basis; (e) contributes technical and policy advice and guidance, as needed, for studies and projects being conducted and managed by other NRC offices or outside agencies.

42 FR 36797

§ 1.32 Office of the General Counsel.

The Office of the General Counsel: (a) provides legal advice and assistance to the Commission and Commission offices with respect to all activities of the NRC; (b) reviews Atomic Safety and Licensing Appeal Board decisions and rulings, decisions reached by staff offices under 10 CFR 2.206, petitions received from members of the public seeking direct Commission action, and rulemaking proceedings involving hearings; and prepares decisions, orders, and rulings for the Commission on these matters; (c) represents, and protects the interests of the NRC in court proceedings, and in dealings with other government agencies, committees of Congress, foreign governments, and members of the public; (d) coordinates and prepares legislative materials in connection with legislation initiated by the NRC and legislations submitted to it for comment; (e) provides advice with respect to questions raised under the conflict of interest laws, Freedom of Information Act, Federal Advisory Committee Act, and Government in the Sunshine Act; (f) provides official written interpretations of the Commission's rules; and (g) performs other functions assigned by the Commission.

§ 1.33 Office of the Secretary.

The Office of the Secretary: (a) develops policies and procedures, and provides secretariat services for the conduct of Commission business and implementation of Commission decisions, including scheduling of Commission business and recording of meetings; (b) issues decisions, orders, and rulings of the Commission, and maintains the official docket of the Commission; and (c) directs and administers the NRC Public Document Room.

§ 1.34 Office of Public Affairs.

The Office of Public Affairs: (a) develops policies and administers programs at NRC headquarters and Regional Offices to inform the public and the news media about NRC policies, programs, and activities; (b) and keeps NRC management informed on media coverage of activities of interest to the agency.

§ 1.35 Office of Congressional Affairs.

The Office of Congressional Affairs: (a) provides advice and assistance to the Commission and NRC staff on all NRC relations with the Congress, and informs them concerning the views of Congress toward NRC policies, plans, and activities; (b) maintains liaison with congressional committees and members of Congress on matters of interest to NRC, and keeps Congress informed on NRC plans, policies, and activities; (c) serves as the contact point for all NRC communications with Congress, reviewing and concurring in all outgoing correspondence to members of Congress and congressional committees; and (d) monitors legislative matters of interest to NRC, and participates in planning and developing NRC's legislative programs.

42 FR 36797

§ 1.36 Office of Investigations.

The Office of Investigations:

(a) Develops policy, procedures and quality control standards for the conduct of all NRC investigations of licensees, permittees, applicants, and their contractors and vendors;

(b) Conducts and supervises investigations within the scope of NRC authority, except those concerning NRC employees and NRC contractors;

(c) Assures the quality of investigations;

(d) Maintains current awareness of inquiries and inspections by other NRC offices to identify the need for formal investigations;

(e) Makes appropriate referrals to the Department of Justice;

(f) Keeps Commission and involved NRC Offices currently apprised of matters under investigation as they affect public health and safety, the common defense and security, environmental quality, or the antitrust laws;

(g) Issues subpoenas where necessary or appropriate for the conduct of investigations;

(h) Maintains liaison with other agencies and organizations to ensure the timely exchange of information of mutual interest.

50 FR 20741

EXECUTIVE DIRECTOR

§ 1.40 Office of the Executive Director for Operations.

The Executive Director for Operations (EDO) is appointed by the Commission, pursuant to the Energy Reorganization Act of 1974, as amended, and performs such functions as the Commission may direct, including the following:

(a) Provides the Commission with assistance on policy, managment, and operational matters. Submits to the Commission for approval such appointments as the Commission shall designate, including Directors of certain divisions and offices. Submits for approval significant changes in the organization.

(b) Supervises and coordinates policy development and operational activities of the following line offices: The Office of Nuclear Reactor Regulation, the Office of Nuclear Material Safety and Safeguards, the Office of Nuclear Regulatory Research, the Office of Inspection and Enforcement, and the Office of Standards Development; and the following staff offices: the Office of Administration, the Office of International Programs, the Office of State Programs, the Office of the Controller, the Office of the Executive Legal Director, the Office of Planning and Analysis, the Office of Management Information and Program Control, the Office of Equal Employment Opportunity, and such other organizational units as shall be assigned by the Commission. The EDO is also responsible for implementation of the Commission's policy directives pertaining to these offices.

42 FR 36797

(c) Recommends to the Commission proposed and final regulations involving significant questions of policy which are needed to protect public health and safety and the environment from effects associated with nuclear facilities and materials subject to licensing, to provide for security of licensed nuclear facilities and safeguarding of licensed radioactive materials, and to assure that activities under facility licenses would not be inconsistent with antitrust laws, as specified in section 105a. of the Atomic Energy Act of 1954, as amended.

(d)(1) Subject to general policy guidance from the Commission and subject to the limitations in paragraph (d)(2) of this section, develops and promulgates rules, as defined in 5 U.S.C. 551(4), in proposed and final form. Notifies the Commission before submitting a final rule to the Federal Register.

(2) The delegated authority in paragraph (d)(1) of this section does not extend to (i) the promulgation of proposed or final rules involving significant questions of policy, or (ii) the promulgation of proposed or final rules in the following areas: 10 CFR Parts 0—Conduct of Employees, 2—Rules of Practice for Domestic Licensing Proceedings, 7—Advisory Committees, 8—Interpretations, 9 Subpart C—Government in the Sunshine Act Regulations, and 110—Export and Import of Nuclear Facilities and Materials.

42 FR 36797

(e) Makes determinations, pursuant to 10 CFR Parts 30, 40, 50, and 70, that exemptions of individual prime contractors or subcontractors of the
* Department of Energy
or the NRC from NRC licensing requirements are authorized by law.

(f) Makes for the Commission, after consultation with the Attorney General, the determinations provided for in section 105c.(8) of the Atomic Energy Act of 1954, as amended, in regard to applications for facility construction permits or operating licenses.

(g) Negotiates and signs agreements, arrangements, and contracts with representatives of foreign countries and international organizations.

(h) Designates which facilities, installations, and real property shall be subject to the prohibitions of 10 CFR Part 160, "Trespassing on Commission Property."

(i) Administers the contracting activities of the Commission.

(j) Administers the Commission's equal employment opportunity program.

(k) Develops and maintains the NRC financial management program.

(l) Acts for the Head of the Agency in making determinations required in administering the NRC labor relations program.

(m) Excercises final determination on appeals under the Privacy Act of 1974, and issues minor revisions of systems of records notices.

42 FR 36797

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* Amended 45 FR 14199

(n) Exercises final determination on appeals under the Freedom of Information Act except for those pertaining to the Office of the Executive Legal Director or to advisory committees, boards, panels, and offices reporting to the Commission.

42 FR 36797

(o) Denies, pursuant to part 2 of this chapter, any petition for rulemaking of a minor or nonpolicy nature where the grounds for denial do not substantially modify existing precedent. The EDO is also responsible for notifying the petitioner with a brief statement of the grounds for denial.

(p) Proposes, in response to a petition for rulemaking, an exemption from licensing requirements for any product containing byproduct, source, or special nuclear material when existing policy provides background or precedent. The EDO is also responsible, in issuing in final form an exemption from licensing requirements for any product containing byproduct, source, or special nuclear material, for making the finding authorized under sections 57d or 81 of the act with respect to exemption of special nuclear or byproduct material, or section 62 of the act with respect to unimportant quantities of source material.

43 FR 28809

≫ (q) Makes or delegates the authority to make the following determinations pursuant to Part 53 of this chapter: (1) The initial determination, pursuant to § 53.27, of whether a person owning or operating a civilian nuclear power reactor cannot reasonably provide adequate spent fuel storage capacity and is diligently pursuing licensed alternatives to the use of Federal storage capacity; (2) whether an exemption should be granted pursuant to § 53.6; and (3) whether an exception should be granted to the filing deadline in § 53.11(b). This authority may not be redelegated beyond the office director level.

50 FR 5548

STAFF OFFICES

§ 1.41 Office of Administration.

The Office of Administration develops and directs polices and programs for personnel administration, organization and management analysis, security and security classification, building management and administrative services, document control, automatic data processing, rules and records, contracting and procurement, and facilities and material license fees.

(a) The Division of Organization and Personnel administers and directs policies, standards, and programs for organization and personnel management activities, including recruitment, training, exexecutive development, staffing services and information, organization and management analysis, labor-management relations, and employee services.

(b) The Division of Security develops, administers, and directs the overall NRC security program; assures the safeguarding of Restricted Data, other National Security Information, and NRC sensitive unclassified matter including NRC telecommunications of significant intelligence value; assures the physical protection of NRC Headquarters buildings, Regional Offices and contractor facilities; and provides advice and assistance on security matters.

(c) The Division of Facilities and Operations Support is responsible for the planning and direction of support programs for facilities and administrative services, including building operations, property, supply, telecommunications, travel, mail, and messenger services.

42 FR 36797

42 FR 36797

(d) The Division of Technical Information and Document Control is responsible for implementing the Paperwork Reduction Act of 1980 (Pub. L. 96–511) and for planning and directing the production (exclusive of writing) and control of NRC documents. Its responsibilities include typing services, publication and graphics; NRC management directives; document evaluation, dissemination, storage, and retrieval; and the preparation and publication of the *Nuclear Regulatory Commission Issuances.*

47 FR 41336

(e) The Division of Automatic Data Processing Support Plans, coordinates, and directs development and utilization of NRC computer services and computer facilities for the storage, retrieval, analysis, and dissemination of information; advises and assists in the development and conversion of scientific and analytical programing and the interpretation of automatic data processing procedures; evaluates expected benefits and costs of computer applications; and provides systems development, programing and operation services for NRC offices.

42 FR 36797

(f) The Division of Rules and Records is responsible for NRC implementation of the Freedom of Information Act and the Privacy Act; directing the coordinating NRC Local Public Document Room activities; preparing the NRC Regulatory Agenda; publishing "NRC Rules and Regulations," and reviewing and preparing notices and amendments to NRC regulations, including the processing of petitions for rulemaking.

47 FR 41336

(g) The Division of Contracts develops and implements agency-wide contracting policies and procedures; directs and coordinates contracting and purchasing activities for NRC, including contractor selection, and negotiation, administration, and closeout of contracts; and provides advice and assistance to NRC program officials concerning procurement regulations and requirements.

(h) The License Fee Management Branch is responsible for collecting fees from licensees and applicants for licenses, as required by 10 CFR Part 170, which sets fees for licensing nuclear production and utilization facilities and nuclear materials. Responsibilities include: reviewing license applications to ensure appropriate fee payment, issuing Orders to Show Cause and Orders of Revocation where licensees violate Commission regulations by nonpayment of license fees, recommending license fee policy changes, and preparing amendments to license fee regulations for Commission approval.

42 FR 36797

§ 1.42 Office of the Executive Legal Director.

The Office of the Executive Legal Director provides legal advice and services to the Executive Director for Operations and offices reporting to that official, including interpretation of laws, regulations, and other sources of authority, advising on the legal form and content of proposed official actions and representing such offices in NRC administrative proceedings; prepares or concurs in contractual documents, interagency agreements, delegations of authority, regulations, orders, licenses, and other legal documents, and prepares legal interpretations thereof; reviews and directs patent law activities; and, except for those matters delegated to the General Counsel, represents the NRC in legal matters with other government agencies, foreign governments, or the public, and in proceedings before administrative bodies outside of NRC.

(a) The Regulations Division prepares, reviews, and advises on NRC regulations and amendments thereto for NRC staff, personnel of other Federal and State agencies, licensees, and others; initiates and drafts administrative procedures for licensing and regulation of the uses of nuclear energy; and provides legal advice on NRC nuclear materials licensing, safeguards, and export licensing matters.

(b) The Operations and Administration Division provides legal advice and assistance in areas of interagency and international agreements, research and technical assistance contracts, patents, proprietary information and other intellectual property, financial and budget matters, security, personnel, and equal employment opportunity, and the administration of the Freedom of Information Act and the Privacy Act.

(c) The Hearing Division acts as counsel for the NRC staff in public administrative proceedings before the Commission, Atomic Safety and Licensing Appeal Boards, Atomic Safety and Licensing Boards, and administrative law judges, in matters relating to licensing of nuclear facilities and materials; and provides legal advice to NRC staff concerning licensing and regulation of nuclear facilities.

(d) The Rulemaking and Enforcement Division acts as counsel for the NRC staff in public administrative proceedings before the Commission, Atomic Safety and Licensing Appeal Boards, Atomic Safety and Licensing Boards, special boards appointed by the Commission, and administrative law judges, in matters involving proposed NRC regulations and the enforcement of NRC license conditions and regulations; and advises the NRC staff regarding enforcement matters involving the amendment, suspension, or termination of licenses, and the imposition of civil penalties.

42 FR 36797

(e) The Hearing Division also acts as counsel for the NRC staff in public administrative proceedings before the Commission, Atomic Safety and Licensing Appeal Boards, Atomic Safety and Licensing Boards, and administrative law judges in matters relating to antitrust aspects of applications for nuclear facility licenses; provides legal advice regarding NRC antitrust responsibilities; and, for operating license antitrust reviews, together with the Antitrust and Economic Analysis Branch of the Office of Nuclear Reactor Regulation, recommends to the appropriate Office Director (NRR or NMSS) whether or not a finding of significant changes should be made.

47 FR 9983

§ 1.43 Office of the Controller.

The Office of the Controller develops and maintains NRC's financial management program. Responsibilities include: Policies, procedures, and standards of accounting, budgeting, pricing, contract finance, automatic data processing equipment acquisition, accounting for capitalized property, and related reporting necessary for NRC direct and contract operations; administration of financial functions for NRC long-range fiscal planning; and liaison on fiscal matters with the General Accounting Office and the Office of Management and Budget and other government agencies, congressional committees (in coordination with the Office of Congressional Affairs), and industry.

(a) The Resources Planning and Evaluation Staff designs systems and develops criteria for NRC program planning and evaluation; evaluates relationships between resource allocation and program performance; and develops overall plans and procedures for measuring and enhancing productivity.

(b) The Division of Accounting develops, maintains, and applies overall policies, principles, standards, and procedures for financial and cost accounting and reporting, automatic data processing equipment acquisition, pricing, and financial arrangements under NRC contracts; is responsible for payroll and travel accounting and other fiscal services; and provides advice and assistance to the Commission, the Executive Director for Operations, and NRC offices on these matters.

42 FR 36797

(c) The Division of Budget coordinates the preparation of the NRC budget, directs funds controls, issues allotments and financial plans; monitors performance under approved budgets and administers NRC authorization and appropriation funding legislation; and maintains liaison with the Office of Management and Budget and (in coordination with the Office of Congressional Affairs) with congressional committees.

§ 1.44 Office of Equal Employment Opportunity.

The Office of Equal Employment Opportunity: (a) develops and recommends for approval by the Executive Director for Operations overall NRC policy providing for equal employment opportunity, without discrimination on the basis of race, color, creed, sex, national origin, age, physical handicap, political affiliation, or marital status; (b) monitors and evaluates NRC's affirmative action program, and recommends improvements or corrections needed to achieve its goals; (c) serves as the NRC contact with local and national public and private organizations on matters relating to equal employment opportunity; and (d) serves as the compliance office for matters relating to Title VI of the Civil Rights Act of 1964 and Title IV of the Energy Reorganization Act of 1974, and 10 CFR Part 4, "Nondiscrimination in Federally Assisted Programs."

§ 1.45 Office of Planning and Analysis.

The Office of Planning and Analysis assesses agency programs; conducts studies and evaluations of management effectiveness; analyzes and develops NRC policies; reviews the activities of offices reporting to and through the Executive Director for Operations; identifies strategies for accomplishing the agency's goals and objectives; and assures consistent implementation of agency policies on cost-benefit analyses.

§ 1.46 Office of International Programs.

The Office of International Programs is responsible for planning, developing, and coordinating staff implementation of NRC's international activities, and for coordinating these activities with those of other agencies. Responsibilities include: (a) Negotiating and implementing regulatory and safety information exchange agreements with other countries and international organizations; (b) coordinating NRC export-import policies and issuing licenses for import and export of nuclear materials and facilities as directed by the Commission; and (c) policy planning related to international safeguards and nonproliferation matters.

§ 1.47 Office of State Programs.

The Office of State Programs is responsible for developing and implementing plans, policies, and programs for the coordination and integration of Federal and State responsibilities in the regulation of nuclear materials and facilities; carrying out NRC's federally assigned "lead-agency" role in providing training and technical assistance to State and local governments to enhance their radiological emergency response planning and operations capabilities; developing NRC's national-level emergency preparedness program; administering the State Agreements program whereby qualified States assume certain NRC regulatory functions; and providing direct program support to NRC in all aspects of State-related activites, including the monitoring of all State legislation and activities affecting the agency.

42 FR 36797

§ 1.48 Office of Management Information and Program Control.

The Office of Management Information and Program Control provides integrated management information and control systems for program planning, and for reporting and analyzing schedules, manpower, budget, and performance of NRC programs; develops and maintains automatic data processing methods for management information systems; administers systems for nuclear plant reliability data collection, compilation, and dissemination of engineering, operational, and failure data; administers agency-wide manpower report system and performance appraisal reports; analyzes and reports on the operating experience of facilities licensed by NRC; and, in coordination with other NRC offices, develops and implements procedures and analyses for research utilization in regulatory judgments.

(a) The Operations Evaluation Division reviews and analyzes operating experience at licensed facilities; prepares computer summaries of events reported by licensees; prepares a quarterly report to Congress on abnormal occurrences; maintains the central repository on radiation exposures; and evaluates operating experience.

(b) The Division of Licensing Information Systems collects, processes, analyzes, and reports information used to appraise licensing program performance.

(c) The Division of Regulatory Information Systems collects, processes, analyzes, and reports information for program performance appraisal of regulatory research programs, operating reactors, nuclear construction and regulatory standards.

PROGRAM OFFICES

§ 1.60 Office of Nuclear Material Safety and Safeguards.

The Office of Nuclear Material Safety and Safeguards was establishd by the Energy Reorganization Act of 1974, as amended. Its functions are: To license and regulate facilities and materials associated with the processing, transport, and handling of nuclear materials; to license operators of production facilities; to review and assess provisions for safety and safeguards against threats, thefts, and sabotage; and to recommend research on safety and safeguards matters.

(a) The Division of Fuel Cycle and Material Safety performs those licensing and regulatory activities specified by the Atomic Energy Act of 1954, as amended, which pertain to the processing, transport, and handling of nuclear materials off the reactor site. These include: Performing safety and environmental reviews for production facilities other than those defined in 10 CFR 50.2(a)(1), licensing radioisotopes, certifying container designs for transportation of radioactive materials, developing and implementing a waste management program, assessing and improving the fuel cycle regulatory base, conducting generic studies on the nuclear fuel cycle, evaluating new technologies for improving safety and environmental protection, and identifying and coordinating related standards and research requirements.

42 FR 36797

(b) The Division of Safeguards develops, implements, and evaluates the overall nuclear safeguards program. This includes initiating NRC safeguards policies and developing, in coordination with the Office of Nuclear Reactor Regulation and other NRC offices, an agency-wide safeguards plan, reviewing the physical security and material control and accounting measures proposed by applicants for nuclear materials licenses; improving the effectiveness of existing domestic and international safeguards systems; planning long-range approaches and identifying associated research requirements; developing and implementing contingency plans to deal with threats, thefts, and sabotage of nuclear material and facilities; evaluating safeguards systems capabilities; and monitoring safeguards operations through information analysis.

§ 1.61 Office of Nuclear Reactor Regulation.

The Office of Nuclear Reactor Regulation, established by the Energy Reorganization Act of 1974, as amended, performs licensing functions associated with the construction and operation of nuclear reactors and with the receipt, possession, ownership, and use of special nuclear and byproduct material used at reactor facilities. It reviews applications and issues licenses for reactor facilities required to be licensed under the Atomic Energy Act of 1954, as amended, and evaluates the health, safety, and environmental aspects of facilities and sites; develops and administers regulations; licenses reactor operators; provides assistance in matters involving reactors or critical facilities exempt from licensing; analyzes reactor design concepts; evaluates methods of transporting nuclear materials and radioactive wastes on reactor sites; and monitors and tests operating reactors, recommending upgrading of facilities and modification of regulations as appropriate.

(a) The Division of Project Management carries out the reactor licensing process for utilization and production facilities other than fuel reprocessing and isotopic enrichment plants; is responsible for managing safety reviews of applications for construction permits and operating licenses for reactors and evaluations of standard plant designs; evaluates technical specifications, compliance with quality assurance criteria, financial qualifications, and plans for dealing with radiological emergencies and potential sabotage; examines and licenses candidates for reactor operator licenses; evaluates operational safety and design modifications of Government-owned nuclear systems and facilities that are exempt from licensing, and evaluates advanced reactor types; and issues, denies, and amends licenses and limited work authorizations.

42 FR 36797

(b) The Division of Site Safety and Environmental Analysis evaluates the safety and environmental aspects of proposed and existing sites for nuclear facilities. It assesses the environmental impact of construction and operation of proposed facilities, performs cost benefit analyses, evaluates consequences of postulated accidents, assesses radiological impacts, and evaluates site adequacy from the standpoints of geology, seismology, demography, meteorology, waste treatment, and other factors. It issues, denies, and amends limited work authorizations.

(c) The Division of Systems Safety carries out detailed safety reviews of reactor applications through the operating license stage; and develops and administers related safety programs and policies governing licensing and authorization of nuclear reactors other than for export. It performs technical reviews and analyses of mechanical, structural, and materials engineering aspects of reactor systems, core performance, auxiliary systems, control systems, mechanical components, reactor structures, and power systems.

(d) The Division of Operating Reactors administers the regulatory program, including safety and environmental reviews, for all reactor facilities licensed for operation; evaluates applications and issues construction permits and operating licenses for nonpower reactors, and, as requested, evaluates operational and design modifications of operating facilities exempt from licensing, owned by the Department of Energy * and the Department of Defense; directs and supervises the processing of applications for license amendments for all licensed reactor facilities; issues, denies, and amends all permits and licenses for nonpower reactors, and amends operating power reactor licenses.

42 FR 36797

(e) The Antitrust and Economic Analysis Branch conducts prelicensing reviews of applications for nuclear facilities to assure that issuance of a license will not create or maintain a situation inconsistent with the antitrust laws; for operating license antitrust reviews, together with the Hearing Division of the Office of the Executive Legal Director, recommends to the appropriate Office Director (NRR or NMSS) whether or not a finding of significant changes should be made; is responsible for ascertaining compliance with license conditions pertaining to antitrust matters; analyzes broad engineering and economic issues in formulating antitrust policy and guidance; and provides specialized technical capabilities in the area of the benefits and costs of power plants and nuclear facilities and need-for-power assessments.

47 FR 9983

§ 1.62 Office of Nuclear Regulatory Research.

The Office of Nuclear Regulatory Research was established by the Energy Reorganization Act of 1974, as amended. It develops, for the Commission, policy options relative to nuclear regulatory research, and implements programs of confirmatory research which the Commission deems necessary for the performance of its licensing and related regulatory functions. Specifically, it sponsors research to establish methodologies, systems, and information to provide a systematic and comprehensive basis for NRC policies and programs; to improve methods and procedures for licensing review, inspection, and enforcement, and other regulatory actions; and to improve regulations and guides. The Office is responsible for implementing and managing research contracts, coordinating research and analytical needs with other Government agencies and private organizations, and coordinating with the Office of International Programs the policy aspects of any joint efforts with other countries or international organizations. It advises NRC staff of pertinent research findings.

42 FR 36797

(a) The Division of Reactor Safety Research plans, develops, coordinates, and supervises experimental and analytical programs to enable NRC to assess the safety of nuclear power reactors. It sponsors research programs dealing with light water reactors, liquid metal fast breeder reactors, high temperature gas reactors, and with related site safety issues.

(b) The Division of Safeguards, Fuel

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* Amended 45FR14199

Cycle and Environmental Research plans, develops, coordinates, and supervises experimental and analytical programs of research on subjects including safeguards, threat analysis, accident prevention in fuel cycle facilities, and health and environmental research.

(c) The Probabilistic Analysis Branch assists the Office Director in planning, developing, coordinating, and supervising programs for the development and application of methods to quantify risk assessment of nuclear power reactors and fuel cycle facilities.

§ 1.63 Office of Standards Development.

The Office of Standards Development develops and recommends standards (e.g., technical regulations and regulatory guides) that NRC needs to regulate nuclear facilities and commercial uses of nuclear materials. These standards deal with radiological health and safety and environmental protection, materials and plant protection (safeguards), and antitrust review in accordance with the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended. The Office also coordinates NRC participation in national and international standards activities.

(a) The Division of Engineering Standards develops standards for nuclear safety in the design, construction, and operation of nuclear reactors and nuclear power plants, other production and utilization facilities, and facilities for the storage, processing, and use of nuclear materials; and for materials safety activities, including the production, use, and transportation of radioactive products; provides technical assistance to NRC staff regarding research, resolution of generic issues, and the development, evaluation, and application of standards to specific safety problems associated with nuclear reactors, nuclear power plants and fuel cycle facilities, transportation of nuclear materials, and the production and use of radioactive products; and, in its assigned areas of responsibility, maintains liaison with and provides technical input to other Federal agencies, the American National Standards Institute (ANSI), professional societies, international agencies (in coordination with the Office of International Programs), and other organizations.

42 FR 36797

(b) The Division of Siting, Health and Safeguards Standards develops standards for protection of licensees' employees, the public, and the environment from the effects of NRC-licensed activities in matters involving radiological protection, environmental effects, and safeguarding of nuclear materials and facilities; provides advice and technical assistance to NRC staff regarding research, resolution of generic issues, and the development, evaluation, and application of standards to specific licensing or other regulatory problems associated with nuclear materials or facilities; and on matters pertaining to its areas of responsibility, maintains liaison with and provides technical input to other Federal agencies, State agencies, ANSI, professional societies, international agencies (in coordination with the Office of International Programs), public interest groups, and other organizations.

§ 1.64 Office of Inspection and Enforcement.

The Office of Inspection and Enforcement develops policies and administers programs for: Inspecting licensees to ascertain whether they are complying with NRC regulations, rules, orders, and license provisions, and to determine whether these licensees are taking appropriate actions to protect nuclear materials and facilities, the environment, and the health and safety of the public; inspecting applicants for licenses, as a basis for recommending issuance or denial of a limited work authorization, construction permit, or an operating license; inspecting suppliers of safety-related services, components, and equipment to determine whether they have established quality assurance programs that meet NRC criteria; investigating incidents, accidents, allegations, and unusual circumstances including those involving loss, theft, or diversion of special nuclear material;[1] enforcing Commission orders, regulations, rules, and license provisions; recommending changes in licenses and standards, based on the results of inspections, investigations, and enforcement actions; and notifying licensees regarding generic problems so as to achieve appropriate precautionary or corrective action. Headquarters Divisions are responsible for developing the inspection program, assuring the technical adequacy of enforcement cases and investigations, preparing notifications to appropriate parties, providing technical management and support for NRC response to incidents, and monitoring and appraising performance of Regional Offices. NRC's five Regional Offices are responsible for carrying out inspections and investigations.

42 FR 36797

(a) The Division of Fuel Facilities and Materials Safety is responsible for those inspection and enforcement functions that pertain to radiological and environmental protection at reactors and fuel facilities and handling of licensed materials, and for criticality control at fuel facilities.

(b) The Division of Safeguards Inspection is responsible for those inspection and enforcement functions that pertain to protection of nuclear materials and reactors.

(c) The Division of Reactor Construction Inspection is responsible for those inspection and enforcement functions that pertain to reactor construction.

(d) The Division of Reactor Operations Inspection is responsible for those inspection and enforcement functions that pertain to reactor operations.

(e) The Executive Officer for Operations Support is responsible for developing requirements for enforcement and investigations; managing assigned investigations; assuring consistency of the enforcement program among the various offices; developing the program for response to incidents; and providing centralized administrative support.

(f) The Executive Officer for Management and Analysis is responsible for budgets, financial control, computer services, management information systems, planning, personnel management, contract administration, technology and inspection training, and management studies and analyses.

(g) Each Regional Office reports to the Director, Office of Inspection and Enforcement, and performs the following functions within its assigned geographical area: inspects applicants, licensees, and others subject to NRC jurisdiction; investigates incidents, accidents, allegations, and other unusual circumstances involving matters subject to NRC jurisdiction; evaluates licensee event reports, and provides response, as appropriate; recommends changes in NRC programs, based on the results of inspections and investigations; and takes enforcement action, to the extent delegated; or recommends enforcement actions to appropriate Headquarters Division of the Office.

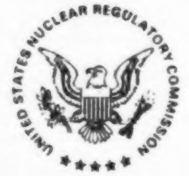
Subpart C—NRC Seal and Flag

§ 1.80 Description and custody of NRC seal.

(a) Pursuant to section 201(a) of the Energy Reorganization Act of 1974, the Nuclear Regulatory Commission has adopted an official seal. Its description is as follows: An American bald eagle (similar to that on the Great Seal of the United States of America) of brown and tan with claws and beak of yellow, behind a shield of red, white, and blue, clutching a cluster of thirteen arrows in its left claw and a green olive branch in its right claw, positioned on a field of white, with the words "United States Nuclear Regulatory Commission" in dark blue and five gold stars outlined in dark blue encircling the eagle. The eagle represents the United States of America and its interests.

42 FR 36797

(b) The Official Seal of the Nuclear Regulatory Commission is illustrated as follows:


UNITED STATES NUCLEAR REGULATORY COMMISSION

(c) The Secretary of the Commission is responsible for custody of the impression seals and of replica (plaque) seals.

§ 1.81 Use of NRC seal or replicas.

(a) The use of the seal or replicas is restricted to the following:

(1) NRC letterhead stationery.

(2) NRC award certificates and medals.

(3) Security credentials and employee identification cards.

(4) NRC documents, including agreements with States, interagency or inter-

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[1] Special nuclear material is defined in 10 CFR Part 70 as "plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material which the Commission * * * determines * * *, but does not include source material * * *."

governmental agreements, foreign patent applications, certifications, special reports to the President and Congress, and, at the discretion of the Secretary of the Commission, such other documents as he finds appropriate.

(5) Plaques. The design of the seal may be incorporated in plaques for display at NRC facilities in locations such as auditoriums, presentation rooms, lobbies, offices of senior officials, on the fronts of buildings, and others designated by the Secretary.

(6) The NRC flag (which incorporates the design of the seal).

(7) Official films prepared by or for the NRC, if deemed appropriate by the Director of the Office of Public Affairs or his designee.

(8) Official NRC publications which represent an achievement or mission of NRC as a whole, or which are cosponsored by NRC and other Government departments or agencies.

(9) Such other uses as the Secretary of the Commission or his designee finds appropriate.

(b) Any person who uses the official seal in a manner other than as permitted by this section shall be subject to the provisions of 18 U.S.C. 1017, which provides penalties for the fraudulent or wrongful use of an official seal, and to other provisions of law as applicable.

42 FR 36797

§ 1.82 Establishment of official NRC flag.

The official flag is based on the design of the NRC seal. It is 50 inches by 66 inches in size with a 38-inch diameter seal incorporated in the center of a dark blue field with a gold fringe.

§ 1.83 Use of NRC flag.

(a) The use of the flag is restricted to the following:

(1) On or in front of NRC installations.

(2) At NRC ceremonies.

(3) At conferences involving official NRC participation (including permanent display in NRC conference rooms).

(4) At governmental or public appearances of NRC executives.

(5) In private offices of senior officials.

(6) As otherwise authorized by the Secretary of the Commission.

(b) The NRC flag must only be displayed together with the U.S. flag. When they are both displayed on a speaker's platform, the U.S. flag must occupy the position of honor and be placed at the speaker's right as he faces the audience, and the NRC flag must be placed at the speaker's left.

§ 1.84 Report of violations.

In order to ensure adherence to the authorized uses of the NRC seal and flag as provided herein, a report of each suspected violation of this part, or any questionable use of the NRC seal or flag, should be submitted to the Secretary of the Commission.

PART 1

STATEMENT OF ORGANIZATION AND GENERAL INFORMATION

PROPOSED RULE MAKING

46 FR 53189
Published 10/28/81
Comment period expires 11/27/81.
Comments received after this date will be considered if practical to do so but assurance of consideration cannot be given except to comments received on or before this date.

Procedures Involving the Equal Access to Justice Act: Implementation

See Part 2 Proposed Rule Making

UNITED STATES NUCLEAR REGULATORY COMMISSION
RULES and REGULATIONS
TITLE 10, CHAPTER 1, CODE OF FEDERAL REGULATIONS—ENERGY

PART 1

STATEMENT OF ORGANIZATION AND GENERAL INFORMATION

STATEMENTS OF CONSIDERATION

42 FR 36797
Published 7/18/77
Effective 7/18/77

PART 1—STATEMENT OF ORGANIZATION AND GENERAL INFORMATION

Codification

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is issuing a statement of its organization and functions that sets out in codified form a description of the major program and staff components of the agency and their functions, lists the location of NRC offices, and describes the NRC seal and flag. This notice, which supersedes notices published on January 22, 1975, and December 11, 1975, complies with provisions of the Freedom of Information Act that each agency shall publish a description of its organization and a list of locations where the public may obtain information.

EFFECTIVE DATE: July 18, 1977.

FOR FURTHER INFORMATION CONTACT:

Betty L. Wagman, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, 301-492-8133.

SUPPLEMENTARY INFORMATION: On January 22, 1975, the Nuclear Regulatory Commission (NRC) published in the FEDERAL REGISTER (40 FR 3520) a notice of the transition organization of its major program and staff components. This notice included a statement that "The organizational requirements of NRC are currently undergoing intensive review by the Commission and further refinements are expected in due course." On December 11, 1975, the NRC published a notice in the FEDERAL REGISTER (40 FR 57722), describing its official seal and restrictions on its use.

Notice is hereby given of a new Part 1 of the NRC regulations, entitled "Statement of Organization and General Information," which is issued pursuant to 5 U.S.C. 552(a)(1), the Freedom of Information Act. This notice supersedes the notices published on January 22, 1975, and December 11, 1975.

Because this notice relates to matters of agency organization and practice, general notice of proposed rulemaking and public procedure thereon are unnecessary.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following new Part 1 of Title 10, Chapter I, Code of Federal Regulations, is published as a document subject to codification.

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43 FR 28809
Published 7/3/78
Effective 7/3/78

PART 1—STATEMENT OF ORGANIZATION AND GENERAL INFORMATION

Additional Functions of Executive Director for Operations

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its statement of organization to delegate to the Executive Director for Operations (EDO) additional functions for dealing with petitions for rulemaking. One delegation authorizes the EDO to deny, pursuant to the Commission's rules of practice, any petition for rulemaking of a minor or nonpolicy nature where the grounds of denial do not substantially modify existing precedent. The other delegation authorizes the EDO to propose, in response to a petition for rulemaking, any exemption from licensing requirements for any product containing byproduct, source, or special nuclear material when existing policy provides background or precedent. These delegations are designed to improve efficiency and timeliness in dealing with petitions for rulemaking.

EFFECTIVE DATE: July 3, 1978.

FOR FURTHER INFORMATION CONTACT:

Mr. Jim Henry, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, 301-443-6910.

SUPPLEMENTARY INFORMATION: On July 18, 1977, the Nuclear Regulatory Commission published in the FEDERAL REGISTER (42 FR 36797) a notice of new part 1 of the NRC regulations, entitled "Statement of Organization and General Information," which was issued pursuant to 5 U.S.C. 552(a)(1), the Freedom of Information Act.

Under § 1.40, the Commission has directed the Executive Director for Operations to perform the following functions, among others:

> (c) Recommends to the Commission proposed regulations to protect public health and safety and the environment from effects associated with nuclear facilities and materials subject to licensing; to provide for security of licensed nuclear facilities and safeguarding of licensed radioactive materials; and to assure that activities under facility licenses would not be inconsistent with antitrust laws, as specified in section 105a of the Atomic Energy Act of 1954, as amended.
>
> (d) Issues proposed amendments to regulations and amendments in final form, where the amendments are corrective or of a minor of nonpolicy nature and do not substantially modify existing regulations; and issues amendments or regulations in final form, if no significant adverse comments or questions have been received on the notice of proposed rulemaking and no substantial changes in text are indicated.

The Commission has reviewed other areas of rulemaking and has determined that responding to petitions for rulemaking would be improved with regard to efficiency and timeliness if the Executive Director for Operations were directed to deny petitions and exempt products from licensing requirements under the conditions set forth below.

DENIAL OF PETITIONS

Under the Commission's regulation, "Rules of Practice," 10 CFR Part 2, the Commission determines whether to grant or deny petitions for rulemaking. If the Commission determines that sufficient reason exists, the Commission may grant the petition and institute a rulemaking proceeding by publishing a notice of proposed rulemaking. In any other case, the Commission denies the petition and notifies the petitioner with a simple statement of the grounds for denial.

This agency practice requires the Commission to issue denials of petitions that involve requests for even the most minor or nonpolicy issuance, amendment, or rescission of any regulation. In addition, the Commission must approve the statement of the grounds for denial in the notification to the petitioner. Consideration of such minor nonpolicy issues does not warrant Commission review.

Accordingly, the Commission is authorizing the Executive Director for Operations to deny, pursuant to 10 CFR part 2, any petition for rulemaking of a minor or nonpolicy nature where the grounds for denial do not substantially modify existing precedent. In furtherance of this function, the Executive Director for Operations is also responsible for notifying the petitioner with a brief statement of the grounds for denial. A denial normally does not prejudice resubmittal of a petition based on new or additional information on the subject.

EXEMPTION OF PRODUCTS

Under existing agency practice, the Commission makes findings authorized under the Atomic Energy Act of 1954, as amended, with respect to exemptions from licensing requirements.

Section 57d. authorizes the Commission to:

> * * * exempt certain classes or quantities of special nuclear material or kinds of uses or users from the requirements for a license * * * when it makes a finding that the exemption * * * would not be inimical to the common defense and security and would not constitute an unreasonable risk to the health and safety of the public.

Section 81 authorized the Commission to exempt byproduct material under the same type of finding.

In the case of source material, section 62 states that:

> * * * licenses shall not be required for quantities of source material which, in the opinion of the Commission, are unimportant.

This agency practice requires the Commission, in responding to petitions for rulemaking requesting exemptions from licensing requirements for products containing byproduct, source, or special nuclear material, to make one of the above findings even when existing policy provides background and precedent. In addition, the Commission must approve publication of a notice of proposed rulemaking even though the actual decision to publish a proposed exemption often depends primarily on a staff technical determination that the exemption, if it becomes effective, would not be inimical to the common defense and security and would not constitute an unreasonable risk to the health and safety of the public. Consideration of such issues does not warrant Commission review when precedents for exemptions provide a background of policy for similar exemptions from licensing requirements.

Accordingly, the Commission is authorizing the Executive Director for Operations to propose, in response to a petition for rulemaking, an exemption from licensing requirements for any product containing byproduct, source, or special nuclear material when existing policy provides background or precedent. In carrying out this function, the Executive Director for Operations is also responsible, in issuing in final form an exemption from licensing requirements for any product containing byproduct, source, or special nuclear material, for making the finding authorized under sections 57d or 81 of the act with respect to exemption of special nuclear or byproduct material, or section 62 of the act with respect to unimportant quantities of source material. If significant adverse comments or questions are received on a notice of proposed rulemaking and substantial changes in text are indicated, the Commission will make the appropriate finding and cause to be published in the FEDERAL REGISTER a notice issuing that exemption in final form or taking other appropriate action.

Because this notice relates to matters of agency organization, management, and procedure, general notice of proposed rulemaking and public procedure thereon are unnecessary and the amendments can be made effective July 3, 1978.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 1, are published as a document subject to codification.

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43 FR 30270
Published 7/14/78
Effective 7/14/78

PART 1—STATEMENT OF ORGANIZATION AND GENERAL INFORMATION

Advisory Committee on Reactor Safeguards

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: This amendment of the Commission's regulation, Statement of Organization and General Information, revises the description of the functions of the Advisory Committee on Reactor Safeguards (ACRS) which was transferred to the Nuclear Regulatory Commission by the Energy Reorganization Act of 1974. The revision adds language to clarify that, upon request from the Department of Energy (DOE) the ACRS performs reviews, provides reports, and advises DOE with regard to the hazards of DOE nuclear activities and facilities.

EFFECTIVE DATE: July 14, 1978.

FOR FURTHER INFORMATION CONTACT:

Gerald L. Hutton, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, 301-492-7211.

SUPPLEMENTARY INFORMATION: Section 1.20 of the Commission's regulation, Statement of Organization and General Information, 10 CFR Part 1, describes the functions of the Advisory Committee on Reactor Safeguards (ACRS) which was transferred to the Nuclear Regulatory Commission by the Energy Reorganization Act of 1974. The revision adds language to § 1.20 to clarify that, upon requests from the Department of Energy (DOE) the ACRS performs reviews, provides reports, and advises DOE with regard to the hazards of DOE nuclear activities and facilities.

Because this amendment relates solely to matters of agency management and procedure, notice of proposed rulemaking and public procedure thereon are not required by section 553 of title 5 of the United States Code, and the amendment may be made effective upon publication in the FEDERAL REGISTER.

Accordingly, pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended and sections 552 and 553 of title 5 of the United States Code, the following amendment to Title 10, Chapter I, Code of Federal Regulations, Part 1, is published as a document subject to codification.

45FR14199
Published 3/5/80
Effective 3/5/80

Minor and Clarifying Amendments

10 CFR Parts 1, 2, 20, 30, 40, 50, 70, 73, 140, 150

Minor and Clarifying Amendments

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The amendments make changes in names and definitions to reflect the transfer of functions from the Energy Research and Development Administration to the Department of Energy made by the Department of Energy Organization Act.

EFFECTIVE DATE: The amendments are effective on March 5, 1980.

FOR FURTHER INFORMATION CONTACT: Royal J. Voegeli, Office of the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone (301) 492–8693.

SUPPLEMENTARY INFORMATION: Pursuant to section 301(a) of the Department of Energy Organization Act (Pub. L. 95–91, 91 Stat. 565 at 577–578, 42 U.S.C. 7151), the functions of the Energy Research and Development Administration were transferred to the Department of Energy on August 4, 1977. To reflect that transfer, the amendments substitute "Department of Energy", "Department" and "DOE" for "Energy Research and Development Administration", "Administration" and "EDRA" wherever they appear in Chapter I. The amendments also define the Department of Energy for purposes of NRC regulations as meaning the Department of Energy to the extent that the Department, or its duly authorized representatives, exercise the EDRA functions transferred to it by the Department of Energy Organization Act.

Because these amendments relate solely to minor matters, it has been found that good cause exists for omitting notice of proposed rule making, and public procedures thereon, as unnecessary, and for making the amendments effective upon publication in the **Federal Register**.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Parts 1, 2, 20, 30, 40, 50, 70, 73, 140 and 150 are published as a document subject to codification.

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45 FR 80270
Published 12/4/80
Effective 12/4/80

10 CFR Part 1

Title Change for Adjudicatory Panel Members

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission has revised its regulations to provide new titles for the members of the Atomic Safety and Licensing Board Panel and the Atomic Safety and Licensing Appeal Panel. Instead of being referred to as a panel "Member" those individuals have been given the title "Administrative Judge".

EFFECTIVE DATE: December 4, 1980.

FOR FURTHER INFORMATION CONTACT: Trip Rothschild, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (202–634–1465).

SUPPLEMENTARY INFORMATION: The Nuclear Regulatory Commission has amended its regulations to provide that members of the Atomic Safety and Licensing Board Panel and the Atomic Safety and Licensing Appeal Panel shall have the title "Administrative Judge." This change is part of the Commission's ongoing program to improve the quality and prestige of its adjudicatory panels. This nomenclature change also more accurately describes the work and functions of the panel members.

Since this amendment relates to internal NRC organization, good cause exists for making this rule immediately effective without seeking public comment.

Pursuant to section 2201(p) of Title 42 of the United States Code, and sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 1, are published as a document subject to codification, to be effective December 4, 1980.

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46 FR 57665
Published 11/25/81
Effective 11/25/81

Change of Address for NRC Region V Office

See Part 20 Statements of Consideration

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47 FR 9983
Published 3/9/82
Effective 4/8/82

Implementation of Commission's Delegation of Authority To Determine Whether There Have Been Significant Changes in Operating License Applicant's Activities or Proposed Activities Since the Construction Permit Antitrust Review

See Part 2 Statements of Consideration

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47 FR 11816
Published 3/19/82
Effective 3/19/82

10 CFR Part 1

Statement of Organization and General Information; Delegation of Rulemaking Authority to Executive Director for Operations

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its statement of organization to reflect the action of the Commission delegating additional rulemaking authority to the Executive Director for Operations. The delegated rulemaking authority, which is to be exercised subject to general policy guidance from the Commission, does not include the promulgation of proposed or final rules involving significant questions of policy or the promulgation of proposed or final rules relating to the conduct of employees, rules of practice, advisory committees, interpretations of Commission regulations, Government in

the Sunshine Act, or export and import of nuclear facilities and materials. The amendment is necessary to inform the public how the Commission's rulemaking activities will be conducted.

EFFECTIVE DATE: March 19, 1982.

FOR FURTHER INFORMATION CONTACT: Jane R. Mapes, Office of the Executive Legal Director, Telephone: (301) 492-8695.

SUPPLEMENTARY INFORMATION: In response to suggestions contained in a study entitled "Review of Delegations of Authority Within NRC," October 4, 1979, and after careful review and consideration, including consideration of the provisions of Reorganization Plan No. 1 of 1980 (45 FR 40561, June 16, 1980), the Commission has approved the delegation of increased rulemaking authority to the Executive Director for Operations (EDO). The delegation of authority is limited to the development and promulgation of rules which do not involve significant questions of policy and provides that the EDO must exercise this authority subject to general policy guidance from the Commission. Rulemaking authority with respect to those parts of the Commission's regulations that relate exclusively to the conduct of Commission employees or to the activities of the Commission or its staff officers (10 CFR Parts 0—Conduct of Employees, 7—Advisory Committees, 8—Interpretations, 9 Subpart C—Government in the Sunshine Act Regulations) or that relate to the conduct of proceedings in which the staff participates as a party (10 CFR Parts 2—Rules of Practice for Domestic Licensing Proceedings, and 110—Export and Import of Nuclear Facilities and Materials) is specifically excluded from the delegation. Despite these limitations, the new delegation of rulemaking authority is significantly broader than that previously delegated to the Executive Director for Operations. Under the former delegation, the EDO was only authorized to issue amendments to the regulations in proposed and final form where the amendments were corrective or of a minor or nonpolicy nature and did not substantially modify existing regulations, or to issue amendments to the regulations in final form if no significant adverse comments or questions had been received on the notice of proposed rulemaking and no substantial changes in the text were indicated.

The Commission believes that delegation of increased rulemaking authority to the Executive Director for Operations should improve the efficiency and effectiveness of the NRC's rulemaking process in several respects. In addition to assuring that all rulemaking is conducted in accordance with the Commission's general policy guidance and that all rules involving significant questions of policy are considered by the Commission itself, the Commission expects this delegation of rulemaking authority to strengthen the systematic development and timely completion of NRC rulemaking initiatives and to expedite the NRC rulemaking process by providing a mechanism for the prompt resolution of differing staff views.

Since these amendments relate solely to matters of agency management and procedure, notice of proposed rulemaking and public procedure thereon are not required by 5 U.S.C. 553 and good cause exists for making the amendments effective March 19, 1982 without the customary thirty days' notice.

A Regulatory Flexibility Act statement is not necessary because that Act does not apply to final rules where notice of proposed rulemaking is not required. The rule contains no recordkeeping, or reporting, or other information collection requirements subject to the Paperwork Reduction Act.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552 and 553, the following amendments to Title 10, Chapter I, Code of Federal Regulations are published as a document subject to codification.

≫ 47 FR 41336
Published 9/20/82
Effective 9/20/82

10 CFR Ch. I, Parts 1, 20, 21 and 73

Minor Clarifying Amendments

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to codify nomenclature changes required by a reorganization of NRC staff activities; to reflect the reassignment of the responsibility for implementing the Paperwork Reduction Act and for preparing the monthly *Nuclear Regulatory Commission Issuances;* to indicate a change in the commercial telephone number for the NRC's Region IV Office; and to announce that the NRC Region IV Uranium Recovery Field Office, located in Denver, Colorado, will become operational on October 4, 1982. The amendments are necessary to inform the public of these administrative changes to NRC regulations.

EFFECTIVE DATE: September 20, 1982.

FOR FURTHER INFORMATION CONTACT: John Philips, Chief, Rules and Procedures Branch, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone 301-492-7086.

SUPPLEMENTARY INFORMATION: 10 CFR Chapter I: On October 16, 1981, the Commission announced a reorganization of NRC staff activities. This reorganization will be accomplished through a regionalization program that will enlarge the role of the NRC's regional offices. The objectives of reorganization are to improve control over requirements imposed on NRC licensees and focus the priorities of the agency and the nuclear industry on those requirements having the greatest safety significance. As a result of the reorganization, certain nomenclature changes are required to reflect the expanded role of the regional offices.

10 CFR Part 1: The NRC has transferred the implementation of the Paperwork Reduction Act and the responsibility for the preparation of *Nuclear Regulatory Commission Issuances,* including managing the collection, review, and publication of Office, Board, and Commission documents, from the Division of Rules and Records to the Division of Technical Information and Document Control. These transfers will result in a more efficient pairing of resources and responsibilities. In addition, on June 16, 1982, the Commission decided to locate the Region IV Uranium Recovery Field Office in Denver, Colorado. The Field Office will be responsible for health, safety, and environmental reviews; the licensing of uranium recovery facilities, which include mills and in-situ operations; providing technical assistance to Agreement States regarding uranium recovery facilities; and performing inspections of these facilities.

On October 4, 1982, the NRC Region IV Uranium Recovery Field Office will become operational. The address for the Field Office is 730 Simms Street, P.O. Box 25325, Denver, Colorado 80225.

10 CFR Parts 20, 21, and 73: (1) Effective August 1, 1982, the commercial telephone number for the NRC's Region IV Office located at 611 Ryan Plaza Drive, Arlington, Texas, will be changed to 817-860-8100; (2) Effective October 4, 1982, the NRC Region IV Uranium Recovery Field Office, located at 730

Simms Street, P.O. Box 25325, Denver, Colorado 80225, will become operational. The telephone number for the Denver Field Office will be (Commercial) 303–234–7232, (FTS) 234–7232.

Because these are nonsubstantive amendments dealing with administrative procedural matters, good cause exists for finding that the notice and comment procedures of the Administrative Procedure Act (5 U.S.C. 553) are unnecessary and for making the amendments effective upon publication.

List of Subjects

10 CFR Part 1

Organization and functions.

10 CFR Part 20

Byproduct material, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Penalty, Radiation protection, Reporting requirements, Special nuclear material, Source material, Waste treatment and disposal.

10 CFR Part 21

Nuclear power plants and reactors, Penalty, Radiation protection, Reporting requirements.

10 CFR Part 73

Hazardous materials—transportation, Nuclear material, Nuclear power plants and reactors, Penalty, Reporting requirements, Security measures.

Under the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552 and 553, the following amendments to 10 CFR Chapter 1 and 10 CFR Parts 1, 20, 21, and 73 are published as a document subject to codification.

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49 FR 16760
Published 4/20/84
Effective 4/20/84

10 CFR Part 1

Functions; Office of Investigations

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of final rulemaking.

SUMMARY: The Office of Investigations was established by the Commission to conduct NRC investigations of licensees permittees, applicants, contractors and vendors. This rule describes the Office of Investigations and its functions.

DATE: April 20, 1984.

FOR FURTHER INFORMATION CONTACT: Polly Schofield, Office of Investigations, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Telephone: (301) 492–7246.

SUPPLEMENTARY INFORMATION: The Office of Investigations (OI) was established to improve NRC's capability to conduct thorough, timely and objective investigations. The office is responsible for the conduct, supervision and quality control of investigations of licensees, permittees, applicants, contractors or vendors undertaken at the request of the Commission, the Executive Director for Operations, Regional Administrators, or on OI's own initiative. This includes investigating allegations of wrongdoing by individuals or organizations other than NRC employees and NRC contractors. For example, allegations regarding falsification of records, intimidation of Quality Control Inspectors and deliberate violations of NRC regulations and requirements fall within the purview of OI.

OI formally commenced operations on July 19, 1982, with the transfer of the investigative staff from the Office of Inspection and Enforcement and from the five NRC Regional Offices to the Office of Investigations. OI consists of a Headquarters complement and five Field Offices. The Field Offices are located at, but are independent of, the five Regional Offices.

OI develops policy, procedures and quality control standards for the conduct of all OI investigations and keeps the rest of the NRC informed of matters under investigation as they affect safety matters. OI also keeps abreast of the NRC inspection program for licensees, permittees, and applicants, and their contractors or vendors, in order to advise the Commission, the Executive Director for Operations, and Regional Administrators of the need for formal investigations. OI also maintains liaison with Federal, State and local law enforcement agencies to ensure timely exchange of information of mutual interest.

Paperwork Reduction Act Statement

This rule contains no information collection requirements subject to the Paperwork Reduction Act of 2980, 44 U.S.C. 3501 et seq.

List of Subjects in 10 CFR Part 1

Organization and Functions (Government agencies).

For reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, notice is hereby given that adoption of the following amendment to 10 CFR Part 1 is contemplated.

≫49 FR 47823
Published 12/7/84
Effective 12/7/84

10 CFR Parts 1, 20, 30, 40, 50, 55, 70, and 73

Minor Correcting Amendments

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to indicate a change in the mailing address for NRC's Region II Office, to correct the zip code for NRC's Region IV Office, and to correct the address of a location where IEEE Std 83–1983 may be inspected. These amendments are necessary to inform the public of these administrative changes to NRC regulations.

EFFECTIVE DATE: December 7, 1984.

FOR FURTHER INFORMATION CONTACT: John Philips, Chief, Rules and Procedures Branch, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone 301–492–7086.

SUPPLEMENTARY INFORMATION: On May 11, 1984, NRC's Region II Office changed its mailing address for the receipt of all non-classified and non-safeguards correspondence. The new mailing address is U.S. Nuclear Regulatory Commission, Suite 2900, 101 Marietta Street, NW, Atlanta, Georgia 30323. The address for classified and unclassified safeguards information remains the same and should read as follows: U.S. Nuclear Regulatory Commission, P.O. Box 2203, Atlanta, Georgia 30301.

In an amendment published on September 28, 1983 (48 FR 44172), an incorrect zip code was printed for NRC's Region IV Office. It should read 76011.

In § 50.73, an incorrect reference has been made with regard to the availability of IEEE Std 83–1983 at the NRC's Public Document Room (PDR), located at 1717 H Street, NW, Washington, DC. This document is not available at the PDR but is available for inspection at the NRC's Technical Library, which is located in the Phillips Building, 7920 Norfolk Avenue, Bethesda, Maryland.

Because these are amendments dealing with agency practice and procedures, the notice provisions of the Administrative Procedure Act do not apply pursuant to 5 U.S.C. 553(b)(A). The amendments are effective upon publication in the Federal Register. Good cause exists to dispense the usual 30-day delay in the effective date because the amendments are of a minor and administrative nature dealing solely with agency procedures.

Paperwork Reduction Act Statement

This final rule contains no information collection requirements and therefore is not subject to the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.).

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is adopting the following amendments to 10 CFR 1, 20, 30, 40, 50, 55, 70, and 73

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50 FR 5548
Published 2/11/85
Effective 3/13/85

10 CFR Parts 1 and 53

Criteria and Procedures for Determining the Adequacy of Available Spent Nuclear Fuel Storage Capacity

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations to establish procedures and criteria for determining whether a person owning or operating a civilian nuclear power reactor cannot reasonably provide adequate spent nuclear fuel storage capacity. This determination is necessary before the Department of Energy may enter into contractual arrangements with the person generating or owning spent nuclear fuel to provide interim Federal storage capacity for limited amounts of spent nuclear fuel. The rule is necessary to meet NRC responsibilities under sections 135 (b) and (g) of the Nuclear Waste Policy Act of 1982.

EFFECTIVE DATE: March 13, 1985.

FOR FURTHER INFORMATION CONTACT: D.R. Hopkins, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: (301) 443-7878.

SUPPLEMENTARY INFORMATION:

Contents

I. Background
II. Responses to Public Comments on the Proposed Rule
III. Section-by-Section Revisions
IV. The Final Rule
V. Other Requirements
VI. Amendatory Text

I. Background

The Nuclear Waste Policy Act of 1982 (Pub. L. 97-425, January 7, 1983, 96 Stat. 2201 *et seq.*, 42 U.S.C. 10101 *et seq.*) establishes a comprehensive framework for the disposal of spent nuclear fuel (SNF) and high-level radioactive waste (HLW) generated by domestic civilian nuclear power reactors.

Subtitle B of Title I of the Act establishes an interim program for the storage of spent nuclear fuel while the repository for ultimate disposal is selected and developed. The primary responsibility for providing interim storage of spent nuclear fuel rests with the persons owning and operating civilian nuclear power reactors. This responsibility is to be implemented through the effective use of existing storage facilities at the reactor sites and by the timely addition of new on-site storage capacity "where practical." The Federal Government has the responsibility to encourage and expedite the provision of interim storage capacity by the reactor owners. In addition, the Federal Government has the responsibility to provide up to 1900 metric tons of storage capacity for spent nuclear fuel from reactors that cannot reasonably provide adequate storage capacity on site.

Section 135(b) of the Act provides that the Department of Energy shall offer to enter into a contract under section 136(a) with a person who owns or generates spent nuclear fuel, that would provide for Federal ownership, transport, and storage of the spent fuel, but only if the Commission makes two affirmative determinations:

1. The person owning and operating a civilian nuclear power reactor cannot reasonably provide adequate spent nuclear fuel storage capacity at the reactor site, or at the site of any other civilian nuclear power reactor operated by that person, when needed to ensure the continued orderly operation of the reactor; and

2. The person generating or owning spent nuclear fuel is "diligently pursuing licensed alternatives to the use of Federal storage capacity" for the storage of spent fuel expected to be generated in the future.

Section 135(g) directs the Commission to establish, by rule, criteria and procedures for making these determinations, and provides the following guidance:

1. The criteria must ensure the maintenance of a full core reserve storage capability at the reactor site, unless the Commission determines that maintenance of such capability is not necessary for the continued orderly operation of the reactor; and

2. The criteria must identify the feasibility of reasonably providing adequate spent fuel storage capacity, taking into account technical, economic, regulatory, and public health and safety factors, through the use of—

a. Expansion of existing storage facilities, including high-density fuel storage racks or fuel rod compaction;

b. Transshipment of spent nuclear fuel to the site of another civilian nuclear power reactor within the same utility system;

c. Construction of new or additional spent nuclear fuel storage facilities at the site of any civilian nuclear power reactor operated by such person;

d. Acquisition of modular or mobile spent nuclear fuel storage equipment, including spent nuclear fuel storage casks, for use at the site of any civilian nuclear power reactor operated by such person; or

e. Such other technologies as may be approved by the Commission.

On April 29, 1983, 48 FR 19382, the Commission published a proposed rule establishing the criteria and procedures for determining the adequacy of available spent nuclear fuel storage capacity.

The proposed rule would have required the person making the request for a Commission determination to provide specified information on spent review of the EDO's initial determination. The basis for not providing a hearing or a petition is that the NWPA does not require such procedures and the determination is not a "proceeding . . . for the granting, suspending, revoking, or amending of any license or construction permit or application to transfer control . . . ," pursuant to section 189a. of the Atomic Energy Act. Numerous comments were submitted on the Commission's delegation of responsibility for an initial determination to the EDO, on the absence of hearing and petition opportunities, and requesting clarification on the type of license amendments, if any, which would be required for a licensee to transfer spent fuel to DOE after an affirmative Commission determination on a request.

A large group of commenters questioned the lack of opportunity to petition the Commission for review of the staff's initial determination. These commenters argued that the unavailability of an opportunity for petition would be contrary to well-informed decision making and to the formation of wise public policy. According to this group, an opportunity to petition the Commission for review would ensure the integrity of the decision making process, while not interfering with decisions which were legitimately defensible. These commenters emphasized the fact that, although technical issues would be considered in making the determination, the decision is essentially a matter of judgement and a policy determination. In addition, they argued that the policy nature of the decision should require the Commission itself, rather than the staff, to make the final determination. One commenter did not believe the Commission should delegate the determination at all. In this commenter's opinion, delegation does not appropriately reflect the specific role that the Congress designed for the Commission in the formulation of nuclear waste policy.

Other commenters, primarily those who might be requesting a Commission determination, viewed the determination process as the first step in what is essentially a contractual process. Therefore, it would not be appropriate to provide an opportunity to anyone outside the contractual process to petition the Commission for review. However, the person requesting the determination should have the opportunity to appeal a negative determination, and to benefit from Commission review before the determination is a final agency action.

In addition to comments on the opportunity to petition, many of the public interest group and State government commenters raised concerns about the potential impacts of spent fuel transfer, transportation, and away-from-reactor (AFR) storage that might eventually result from an affirmative Commission determination. These potential onsite and offsite impacts led these commenters to request a public hearing on a determination. In addition, because an affirmative determination could lead to alteration of the facility, one commenter argued that the determination process could reasonably be construed as a proceeding for amending a license, and therefore would require a hearing under section 189a of the Atomic Energy Act. This commenter requested clarification on whether a determination request would be a proceeding to amend a license, and if not, what license amendments would be required before any transfer of fuel could take place pursuant to an affirmative determination. Another commenter recommended that there be a mandatory hearing before any transfer of spent fuel occurs.

In response to these comments, the Commission believes that a fuller explanation is warranted of the significance of its Part 53 determination in relation to the Federal interim storage program under the Nuclear Waste Policy Act. The purpose of a determination under Part 53 is to provide a basis for contract negotiations between the Secretary of the Department of Energy and the person owning or generating the spent nuclear fuel for which the determination is sought. It is simply a determination of a person's eligibility for Federal interim storage and, as such, will assist the Secretary in planning and seeking the necessary approval to provide such storage at one or more sites. An affirmative determination under Part 53 does not relieve either the licensee or the Secretary from complying with all applicable Commission regulations and licensing requirements.

The Nuclear Waste Policy Act does not require any particular procedures for a Commission determination of inadequate spent fuel storage capacity under section 135(b) of that Act. Rather, section 135(g) directs the Commission to propose procedures and criteria for making such a determination, which the Commission has done in proposed Part 53. A Commission determination under Part 53 is not a "proceeding under [the Atomic Energy] Act for the granting, suspending, revoking, or amending of any license or construction permit, or application to transfer control . . .," under section 189a. of the Atomic Energy Act. A Part 53 determination does not constitute a license or other form of authorization to alter the facility, amend the license conditions, or transfer the spent fuel.[1] Rather, it is a prerequisite to a contractual process, authorized in the Nuclear Waste Policy Act, that may lead to actions requiring a license under the Atomic Energy Act. Because a license is not involved, the Commission has concluded that an opportunity for a hearing on a Part 53 determination request is not required.[2]

Section 135(a) of the Waste Act directs the Secretary to provide not more than 1900 metric tons of capacity for the storage of spent nuclear fuel from civilian nuclear power reactors. Such capacity may be provided through one or more of three methods as the Secretary determines to be appropriate. First, the Secretary may use available capacity at one or more facilities owned by the Federal government of January 7, 1983 (the date of enactment of the NWPA). Second, the Secretary may acquire modular or mobile spent nuclear fuel storage equipment and provide it to a person generating or owning spent fuel, at the site of any civilian nuclear power reactor operated by that person or at any site owned by the Federal government on January 7, 1983. Third, the Secretary may construct storage capacity at any site of a civilian nuclear power reactor.

The first method, although not subject to licensing under the Atomic Energy Act and Section 202 of the Energy Reorganization Act, requires a Commission determination that the Secretary's use of available storage capacity at an existing Federally owned facility will adequately protect the public health and safety. The Commission will consider what fuel storage capacity and need, the feasibility of storage alternatives, and evidence that licensed storage alternatives were being diligently pursued.

The criteria for making the determination on the ability of the person to reasonably provide adequate storage capacity included consideration of any technical, economic, regulatory, and public health and safety constraints on the implementation of specified storage alternatives. Examples were also provided of the specific constraints that would be considered in making the Commission determination.

In order to determine whether the person making the request was diligently pursuing licensed storage alternatives, the proposed rule required Commission consideration of whether the person has initiated timely actions either to provide the necessary storage capacity, or to seriously investigate the feasibility of providing the necessary storage capacity.

Section 135(g) of the Act requires the Commission's criteria to ensure the maintenance of full core reserve storage capability at the site of the reactor unless the Commission determines that such capability is not necessary for the continued orderly operation of the reactor. While a full core reserve capability is not an NRC licensing or safety requirement, maintenance of full core reserve would enhance safety to some extent, and would also be needed to prevent extended reactor outages in the event a core must be discharged in order to inspect the reactor pressure vessel and perform other routine and unscheduled maintenance operations. Although a reactor can be quickly and safely shut down without a full core reserve storage capability, if the core had to be discharged the reactor would have to remain shut down while arrangements for shipping and storage were made and executed. During this time, the utility would have to purchase supplemental power at substantial additional cost to its customers, which would not represent orderly operation of the reactor. The proposed rule contained a generic finding that, for the purposes of a determination under this part, full core reserve is necessary for the orderly operation of the reactor.

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[1] The typical Part 50 operating license and the Commission's regulations in 10 CFR 30.41, 40.51, and 70.42 authorize a licensee to transfer spent fuel to an authorized recipient. The Department of Energy becomes an "authorized recipient" in these circumstances when it secures the necessary license or determination from the Commission, as provided in section 135(a) of the Nuclear Waste Policy Act of 1982, section 202 of the Energy Reorganization Act of 1974, and the Atomic Energy Act of 1954.

[2] Neither the Nuclear Waste Policy Act nor the Atomic Energy Act requires a hearing for a Part 53 determination. Congressman Ottinger's remarks concerning NRC hearings, made during the House floor debates, appear to have been made in consideration of the need for NRC licensing of facilities used for Federal interim storage of spent nuclear fuel and the corresponding opportunity for a hearing that Section 189a. Of the Atomic Energy Act provides. *See*, 128 Cong. Rec. H 8533 (daily ed. Nov. 29, 1982), 128 Cong. Rec. H 8796–97 (daily ed. Dec. 2, 1982).

The proposed rule did not provide an opportunity for public comment, either on the submission of a request for a determination, or on the Executive Director for Operations' (EDO) initial determination. However, Commissioner Asselstine specifically requested public comment on whether a short public comment period should accompany a request for a determination.

The proposed rule placed responsibility for the initial determination on the EDO, or his or her designee. This initial determination could be reviewed by the Commission at its discretion. No right of appeal of the EDO's decision was provided.

Persons with an immediate need for a determination could submit a request upon publication of the proposed rule in order to allow the staff to begin consideration of the request. However, the formal date of receipt of the request would be deemed to be the effective date of the final rule. No such requests have been submitted.

II. Responses to Public Comments on the Proposed Rule

A total of thirty-three letters of comment were received from State governments, public interest groups, electric utilities, architect-engineers, special interest groups, the Department of Energy, and individual members of the public. The comments addressed a wide range of issues and have been placed in the following categories:

1. Public Participation;
2. Commission Involvement;
3. Limitations on the Time of Filing;
4. Nature of the Determination;
5. Contents of a Request;
6. Full Core Reserve;
7. Storage Alternatives;
8. Criteria on Diligence;
9. Criteria on Feasibility;
10. NEPA; and
11. Miscellaneous.

1. Public Participation

The proposed rule contained no provision for public comment on individual requests for a Commission determination. However, Commissioner Asselstine specifically requested comments on this issue, and several commenters addressed it, both pro and con. Those in support of a public comment provision cited the Commission's need for a complete and accurate record on which to base a decision and the essential fairness of extending an opportunity to comment to those affected by a Commission determination. Public comment would help to ensure that information is brought to the Commission's attention that might not otherwise be presented if the Commission relied exclusively on the utility requests for the determination. Several commenters also noted that the denial of an opportunity for public comment was not in keeping with the spirit of the consultation and concurrence established between the Federal government and the States in the Nuclear Waste Policy Act of 1982. One commenter advocated public comment not only on the request for a determination, but also on the NRC's initial determination.

The commenters opposed to a public comment provision felt that it would involve unnecessary delay, paperwork, and the expenditure of staff resources. In addition, these commenters did not believe that public comment would be appropriate because the Commission determination will be based solely on technical findings, would have no direct environmental impact, is merely the first step in a contractual process, and does not involve a license. Finally, one commenter cautioned that the solicitation of public comments would imply an obligation for the Commission to specifically respond to these comments.

After consideration of these comments, the Commission has decided to provide for a 30-day public comment period in the interest of obtaining as much information as possible on an individual request. Although the rule requires that sufficient and accurate information be submitted by the person making a request for a determination, a more complete understanding of the situation may be generated by providing an opportunity for the presentation of other perspectives. Any resulting increase in the staff resources expended on a determination will be outweighed by furthering the objective of obtaining more complete information on the request. Therefore, § 53.11(c) has been revised to provide an opportunity for a 30-day public comment period. Although the Commission is interested in obtaining public comment, the solicitation of public comments on a request for a determination is an optional procedure that is not required by either the Atomic Energy Act or the Nuclear Waste Policy Act (NWPA). Consequently, a detailed comment analysis need not be prepared. The Commission will consider all comments in making its determination, and will address any substantial comments received in the context of the initial determination.

2. Commission Involvement

As did the proposed rule, the final rule provides that the initial determination on a request shall be made by the Executive Director for Operations (EDO), or his or her designee. This initial determination is subject to Commission review at its discretion. The final rule does not provide an opportunity for a hearing in connection with a request for a Commission determination, nor does it permit a person to petition the Commission for procedures may be appropriate for making that determination in the event that the Secretary proposes to provide interim Federal storage capacity by that method.

The other two methods would be subject to licensing under the Atomic Energy Act and section 202 of the Energy Reorganization Act of 1974. Depending on the storage method proposed and the arrangements made, the required licensing actions could include a reactor license amendment under 10 CFR Part 50 or a license for an independent spent fuel storage installation under 10 CFR Part 72. An opportunity for a hearing would be provided in section 189a. of the Atomic Energy Act for such licensing actions. Admissible contentions concerning the substance of a Part 53 determination could be explored in that context.

In situations where DOE would utilize an AFR facility to store spent fuel that was a part of the Federal interim storage program, section 137(a) of the Nuclear Waste Policy Act requires DOE to comply with applicable NRC and Department of Transportation (DOT) regulations. The applicable Commission regulations are contained in 10 CFR Part 71, "Packaging and Transportation of Radioactive Material," (48 FR 35600, August 5, 1983). Under Part 71, DOE would be required to use a shipping cask that has received an NRC certificate of compliance certifying that the cask satisfies the relevant NRC safety criteria (10 CFR Part 71, Subpart E) and to obtain NRC approval of a quality assurance program designed to provide adequate confidence that the packaging system will perform satisfactorily (10 CFR Part 71, Subpart H). Section 71.97 of 10 CFR Part 71 would require DOE to provide advance notification to the government of any State where the spent fuel is shipped "to, through, or across the boundary of the State." Section 73.37 of the Commission's regulations establishes requirements for the physical protection of spent fuel while in transit. Additional assurance that any impacts from the transportation of spent fuel will be prevented or mitigated will be provided by DOE's obligation to comply with the DOT regulations contained in 49 CFR Parts 171 to 177. Furthermore, section 135 of the Nuclear Waste Policy Act makes extensive provision for the protection of public health and safety, and the environment, and for the full participation by State and Indian Tribal government in the AFR storage decision making process.

In addition to utilizing a Federal AFR facility or site, sections 135(a)(1) (B) and

(C) of the Nuclear Waste Policy Act authorize DOE to store fuel enrolled in the Federal interim storage program at the site of a civilian nuclear power reactor. In providing storage capacity at the site of the civilian nuclear power reactor, section 135(a)(4) of the Nuclear Waste Policy Act requires DOE to comply with any applicable requirements for the licensing or authorization of the particular storage method used. Therefore, all NRC requirements for on-site spent fuel storage, including any hearing requirements, will apply to DOE actions in this area. Likewise, if a licensee seeks permission to implement an alternative to the Federal interim storage of spent fuel, NRC regulations will apply, including an opportunity for a hearing.

In summary, the existing legal framework provides adequate consideration of the potential impacts of spent fuel storage and transportation, including opportunities for public participation, whether in relation to DOE implementation of the Federal interim storage program, or the implementation of a specific spent fuel storage alternative by an NRC licensee. Therefore, the Commission does not believe it necessary to provide additional hearing or petition opportunities in connection with the determination of adequate capacity.

As a final point, although judgement will be involved in making the spent fuel capacity determination, the decision essentially involves an informed evaluation of whether a particular factual situation satisfies the criteria established in section 135(g) of the Nuclear Waste Policy Act, as implemented by the Commission in 10 CFR Part 53. As such, it is not a policy determination, and delegation of the initial decision to the NRC staff is appropriate. Delegation is not prohibited by the Nuclear Waste Policy Act, and section 209 of the Energy Reorganization Act permits the delegation of authority to the EDO.

3. Limitations of the Time of Filing

Many commenters from the electric utility industry expressed dissatisfaction with the provisions of proposed § 53.11(b) which control the timing of a request for a determination. Proposed § 53.11(b) required requests for a determination to be filed not longer than two years before the anticipated loss of full core reserve, and in any case, before June 30, 1989. Utility commenters stated that the prohibition of the filing of a request earlier than two-years before anticipated loss of full core reserve was unjustified and not conducive to effective utility and DOE planning. These commenters recommended that requests for a determination be entertained at any time that the need can be demonstrated, preferably earlier than 2 years in advance of the anticipated loss of full core reserve. Finally, these commenters noted that the combination of the 2-year filing time and the June 30, 1989 deadline would prevent utilities from obtaining interim storage if full core reserve would be lost after June 30, 1991. One commenter also suggested that in the event that Federal interim storage were fully committed and used, the Commission should provide for a suspension on the processing or acceptance for filing of requests. A few commenters also recommended that the June 30, 1989 deadline be eliminated in the event the 1998 completion date could not be met or, in the alternative, that the Commission extend the acceptance of requests beyond June 30, 1989 if the Commission determined that the first nuclear waste repository would not be fully operational by 1998.

One of the Commission's objectives in establishing the 2-year filing requirement was to provide DOE with sufficient time to plan for potential Federal storage needs. The 2-year period was selected on the basis of the normal refueling cycles for nuclear power plants, allowing at least one complete refueling cycle before loss of full core reserve. The Commission believed that this would be early enough to give DOE sufficient lead time for planning, but also late enough in the process for a utility's potential need for interim Federal storage to be established. The June 30, 1989 limitation on filing a request for a determination was established because of the January 1, 1990 limitation established in section 136(a) of the Nuclear Waste Policy Act on DOE contracts for the storage of spent fuel. In light of the fact that the Commission is given 6 months to make a determination after a request is filed, June 30, 1989 would be the last possible date that a request could be given a full 6-month review before DOE contracting authority expired.

After considering the public comments, the staff believes that the 2-year filing limitation may unnecessarily prevent the filing of requests for a determination for which adequate justification exists well in advance of 2 years before anticipated loss of full core reserve. The better practice would be to allow the filing of a request at any time that a need can be demonstrated subject to the June 30, 1989 filing deadline. It should also be emphasized that if a request for a determination is based on circumstances that are too remote and speculative to allow an informed Commission determination, the Commission, under § 53.27, may deny the request.

Elimination of the 2-year filing limitation would allow those persons who, for unforseen reasons, cannot implement a planned spent fuel storage alternative to file a request for a determination at any time. Deletion of the 2-year filing limitation would also allow persons who might need Federal interim storage in or beyond 1992 to file a request before the June 30, 1989 filing deadline. The Commission did not intend to preclude anyone from establishing a need for Federal interim storage before the filing deadline. However, it should be noted that the longer the time period between the filing of a request and when Federal interim storage is actually needed, the more likely it is that other spent nuclear fuel storage alternatives will be available.

The June 30 1989 filing deadline has been retained. The Commission believes that, in most cases, persons needing Federal interim storage will be able to anticipate their need well in advance of that date. However, the final rule provides that an exception to this requirement may be granted if the request is likely to be processed before the DOE contract authority expires and the person making the request has shown good cause for the failure to file on time.

If a need exists for an expanded Federal interim storage program, the Congress would be the appropriate forum to address this issue. However, because it is possible that Federal interim storage may be fully committed before the January 1, 1990 deadline on DOE contracting authority, § 53.11(e) of the final rule provides that the Commission may suspend the processing or acceptance of requests in this eventuality.

4. Nature of the Determination

A number of commenters raised a variety of concerns on the nature of the Commission determination. The DOE recommended that the Commission place a 60-day time limit on an eligibility determination ot encourage the utility to enter into a contract with DOE in a timely manner. According to DOE, a signed contract is necessary to ensure that revenues will be available to cover the costs of the Federal interim storage program. A related concern of DOE is the provision in § 53.27(c) of the proposed rule which allows the Commission to attach conditions to an affirmative determination. The DOE recommended deletion of this provision in order to provide more certainty on the amount of interim Federal spent fuel storage capacity that will be required. However, a utility comment on the same provision recommended that the conditional determination be utilized to allow the Commission to find a utility eligible for Federal interim storage for a limited period of time and a limited amount of fuel until another alternative became available. This would give the utility access to Federal interim storage until another alternative could be implemented, assuming of course that the utility continued to make diligent, good faith efforts to implement other alternatives. According to this commenter, § 53.27(c) should be construed to allow for eligibility for Federal interim storage until the uncertainties related to the implementation of other alternatives are resolved.

A number of nuclear industry commenters suggested that the Commission determination should include coverage of emergencies in which a utility needed to transfer spent fuel to an AFR facility in order to repair accidental damage to a spent fuel pool. According to these commenters, Federal interim storage should be available for these types of emergency situations. On a related point, one commenter recommended that the Commission insert a provision into the final rule that would allow the Commission to grant exemptions to the regulations contained in 10 CFR Part 53 if the exemption was authorized by law and in the public interest. Other nuclear industry commenters recommended that the determination process should include coverage of situations where a utility was storing spent fuel offsite but would eventually need to transfer the fuel back to the reactor site. Most of these commenters stated that the spent fuel presently stored at AFR facilities should be included in the calculation of when full core reserve capability at a particular site would be depleted. One commenter expanded on this idea by recommending that even if the amount of spent fuel stored offsite would not deplete full core reserve capability when added to the fuel stored at the reactor, it would still be in the public interest to ship the offsite fuel directly to a Federal facility, rather than returning it to the reactor site.

A number of other concerns related to recommendations that the Commission clearly state in the final rule that an affirmative determination establishes eligibility for the Federal interim storage program; that the final rule should specify that an affirmative determination would only cover spent fuel that is five years or older; and that the final rule should restrict participation in the Federal interim storage program to utilities only, based on the fact that the purpose of the program was to prevent the shutdown of operating reactors.

While the Commission is sympathetic to the needs of DOE to ensure that funds are available to cover the costs of the storage program, the Commission does not believe that it is appropriate for the Commission to place a time limit on the duration of an eligibility determination for the sole purpose of encouraging utilities to enter into a contract with DOE. The Commission's primary responsibility under section 135(b) of the Nuclear Waste Policy Act is to determine whether a person filing a request satifies the statutory criteria for participation in the Federal interim storage program. It would not be appropriate for the Commission to dictat, when, and if, an affirmative determination should be utilized, except in those cases where the Commission had attached conditions to an affirmative determination. However, these conditions would be related to the satisfaction of the statutory criteria, and not to other purposes, such as encouraging a utility to contract with the DOE. Furthermore, it does seem possible, and appropriate, for DOE to establish a standard clause in its interim fuel storage contract that would require a utility to enter into the contract at some specified time in advance of the need-for-storage date specified in an affirmative Commission determination. As a final point, the Commission would note that, to the fullest extent practicable, an affirmative determination will issue in only those cases where a utility has no other recourse but Federal interim storage. Therefore, affirmative determinations should be a reliable guide to the amount of storage capacity necessary.

The provision for a conditional determination contained in § 53.27(c) of the proposed rule was designed to provide the Commission with the flexibility to tailor an affirmative determination to the particular facts of a request. The Commission reaffirms its need for this type of flexibility and has not deleted the provision as recommended by DOE. However, the Commission emphasizes that the consideration of any uncertainties regarding the implementation of an alternative to Federal interim storage is an integral part of the Commission review under section 135(b) of the Nuclear Waste Policy Act. This review requires a decision as to whether the uncertainties would make a particular alternative infeasible. The mere existence of uncertainties, in and of themselves, would not necessarily result in an affirmative determination. Therefore, it would not be appropriate, as suggested by the utility commenter, for the Commission to issue an affirmative determination merely because uncertainties exist, leaving resolution of those uncertainties for a later date. The Commission's responsibility is to attempt to determine which of those uncertainties would render a particular alternative infeasible. However, in selected instances the Commission may use the provisions of § 53.27(c) to condition an affirmative determination on there being no change in the circumstances that render a particular alternative infeasible.

The Commission has not included any provision in the final rule for emergency situations related to the need to offload spent fuel to an away-from-reactor facility (AFR) in order to make repairs to a spent fuel pool. Although a Federal facility may ultimately be used to alleviate a particular utility's problem in this regard, the Commission does not believe that the Federal interim storage program was intended to address this problem. Rather, the intent was to provide a limited amount of storage where there is an unavoidable shortfall between the spent fuel generated and a utility's long-term program to meet its storage needs.

The Commission has added an exemption provision as § 53.6 of the final rule. Because many of the requirements of the rule are taken directly from the Nuclear Waste Policy Act of 1982, no exemptions can be given to their provisions. The exemption provision is, therefore, not expected to be put to much use. It is included to give the Commission the flexibility to implement the provisions of the Act in ways not now contemplated by the regulations in 10 CFR Part 53.

The Commission has revised the final rule to clarify that a utility may include, as a basis for its request for a determination, spent fuel currently stored at an AFR site which is eventually slated for return to the reactor site. Section 53.12(c)(5) of the final rule requires the submission of information on the amount and location of spent fuel stored offsite, and the anticipated duration of offsite storage. As intended by the proposed rule, a person may request a determination based on the full core reserve at a reactor site being depleted by the pending return of offsite spent fuel. If the criteria on feasibility and diligence are met, the resulting affirmative determination could then be used to allow the utility to contract with DOE for the fuel stored offsite. However, if the criterion on the loss of full core discharge capability would not be satisfied with the return of the offsite spent fuel, the Commission would deny the request for a determination.

The Commission has decided not to add a provision to the final rule specifying that the spent fuel covered by a Commission determination be 5 years old or older. The Commission's responsibilty under section 135(b) of the Nuclear Waste Policy Act is to determine if a person cannot reasonably provide adequate spent fuel storage capacity. Restrictions on the type of spent fuel accepted by DOE for Federal interim storage is more properly addressed in DOE contract provisions, or in the licensing or safety review of Federal interim storage capacity. The Commission regulation applicable to any Federal interim storage facility subject to licensing, 10 CFR Part 72, limits storage to spent fuel aged for at least one year. The particular storage method proposed by DOE could require longer decay.

The Commission has revised the final rule to permit the filing of a request, by a "person owning 'or' operating a civilian nuclear power reactor." Although the Nuclear Waste Policy Act used both this phrase and the phrase "person owning 'and' operating a civilian nuclear power plant," (emphasis added), several commenters suggested that the use of the disjunctive "or" was more appropriate, because there are cases where the owner of the spent fuel may not be the operator of the nuclear power reactor at which the spent fuel was generated. The Commission agrees and has revised the rule accordingly. As a final point, the Commission does not feel that it would be appropriate, or necessary, to specify that only utilities are eligible to make a request. Because the determination concerns the ability of the reactor owner or operator to provide additional storage capacity at the site, the reactor owner or operator would be the appropriate person to request a Commission determination and to supply the necessary information. Likewise, the Commission does not feel it is necessary to insert a provision in the final rule to the effect that an affirmative determination establishes eligibility for participation in the Federal interim storage program. This is explicitly provided in the statutory provisions and there is no need to state this in the rule.

5. Contents of a Request

A number of comments were received on the contents of a request required by proposed §§ 53.12 and 53.13. One State, while agreeing that the proposed rule accurately specified most of the information necessary for an informed Commission determination, recommended that the Commission change the order in which the information is requested in order to emphasize the legislative intent of the Nuclear Waste Policy Act. Specifically, the State requested that the Commission first request information on "what measures might reduce the need for Federal storage" and then request information on "how much fuel the utility wishes to transfer to Federal storage." Comment Letter No. 9, at 5. [3] According to the State, requesting the information in this order would emphasize that a heavy burden of proof rests on the utility to demonstrate that no other alternatives to Federal interim storage are available. The Commission assumes that this comment is directed towards the fact that proposed § 53.12 requests general data on a number of issues, including the amount of spent fuel for which Federal interim storage would be necessary, while proposed § 53.13 requests specific information on alternatives to Federal interim storage. In response, the Commission would note that the format of the proposed rule was selected as the clearest method for organizing the information that the Commission would need to make a determination. There was no intent to convey any particular attitude about the purpose or implementation of the Federal interim storage program. The Commission notes that the format of the proposed rule does focus on that aspect of the determination process, alternatives to Federal interim storage, of most concern to the State. Moreover, an affirmative determination will not be made unless the requestor demonstrates that alternatives to Federal interim storage cannot reasonably be provided in a timely manner. Also, it is equally logical to state the magnitude of need before addressing the lack of reasonable alternatives that might reduce the need. Accordingly, the Commission believes that reordering of the information required in §§ 53.12 and 53.13 is not required. However, the State also suggested a number of useful clarifications to the information requested in § 53.12 regarding the operations which result in excess spent fuel over available storage capacity. These have been incorporated into the final rule.

Several industry commenters recommended deletion of § 53.12(c)(5)(ii) which requested information on the anticipated date of reactor shutdown if full core discharge capability is not maintained. These commenters noted that this provision would be inconsistent with § 53.30(b) which provided that the Commission ensure the maintenance of a full core reserve at the site of the civilian nuclear power reactor. The Commission agrees and has deleted § 53.12(c)(5)(ii) from the final rule. Other industry comments recommended deletion of the reference in § 53.12(c)(3) to the "location of spent nuclear fuel assemblies," because it could be misconstrued to mean the precise location of spent fuel assemblies within the spent fuel pool itself, rather than the location of assemblies in terms of various storage areas at the reactor site. The Commission agrees and has deleted any reference to "location" from § 53.12(c)(3). The required description of the type and capacity of fuel storage facilities requested in § 53.12(c)(1) will already provide the requisite information on location. A final industry comment on § 53.12 requested revision of § 53.12(c)(1) to read "The type and capacity of existing and planned spent nuclear fuel storage facilities at the reactor site for the next ten years and for the remainder of the license term, assuming a reasonable date for Federal ultimate disposal availability." Comment Letter No. 25, at 2. According to this commenter, the revision would reflect that accurate planning for spent fuel storage for a reactor, particularly for those whose operating life extends beyond the year 2005, is dependent on the expected availability of a permanent disposal site. While this may be true, the Commission does not believe it necessary to add this "assumption" to the final rule. Persons making a request may specify in § 53.12(c)(1) how their spent fuel storage plans are affected by the availability of the permanent repository.

Various industry commenters made a number of recommendations in regard to the specific information requested in § 53.13 on the feasibility of implementing spent fuel storage alternatives. These comments also affect § 53.30(a), which sets forth the criteria for making the determination on feasibility, and utilizes the information submitted under § 53.13(a). First, industry commenters objected to the use of the word "prevent" in § 53.13(a) of the proposed rule. This section requests information on "technical, economic, regulatory or public health and safety constraints that would 'prevent' the use of any of the alternatives set forth in paragraph (c) of this section." (Emphasis added.) Industry commenters suggested that "prevent" is inappropriate, and also inconsistent with section 135(b)(1)(A) of the Nuclear Waste Policy Act, which directs DOE to enter into contracts for spent fuel storage where adequate capacity "cannot 'reasonably' be provided." (Emphasis added.) Therefore, these commenters recommended substitution of a phrase such as "render unreasonable" or "render impracticable" for the word "prevent," to describe the effect of various constraints on the implementation of storage alternatives. The commenters pointed out that there may be circumstances that do not actually prevent the implementation of an alternative (in the sense of making it impossible), but may make implementation impractical or unreasonable. The Commission agrees that its rules should conform to the statutory standard. Accordingly, § 53.13(a) of the final rule has been revised to substitute the phrase "that would make the implementation of any of the alternatives unreasonable" for the phrase used in the proposed rule, "that would prevent the use of any of the alternatives . . . ." section 53.30(a) has also been revised to substitute the word "unreasonable" for the word "impractical."

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[3] Copies of the public comments on the proposed rule published April 29, 1983 (48 FR 19382) are available for inspection, or copying for a fee, at the NRC Public Document Room, 1717 H Street NW., Washington, D.C.

Second, industry commenters objected to the use of the phrase "extraordinary costs to consumers" in § 53.13(a) and in § 53.30(a)(5). Section 53.30(a) of the proposed rule sets forth a number of factors that the Commission will consider in determining whether implementation of an alternative to Federal interim storage is unreasonable. The criterion is proposed § 53.30(a)(5) read:

> Extraordinary costs of implementation that are clearly unreasonable in view of the amount of additional storage capacity needed or the time for which additional capacity is needed.

The industry commenters argue that the legislative intent would be satisfied by simply using a "clearly unreasonable" standard, rather than also including the "extraordinary cost" consideration. Accordingly, they recommended substituting "clearly unreasonably" for "extraordinary" in § 53.13(a), and deleting "extraordinary costs" from § 53.30(a)(5). Furthermore, they recommended that the entire § 53.30(a)(5) standard be revised to allow consideration of "unreasonable costs which are due to the unit costs of additional spent fuel storage capacity being substantially higher than the costs of Federal interim storage." In addition, one industry commenter recommended that the industry should be required to submit information on the entire costs of providing the additional capacity necessary, the time for which the additional capacity is necessary and the period for recovery of costs, and comparative cost information. Finally, this commenter recommended that the final rule should invite the submission of any information, in addition to that specified, which is relevant to any of the criteria in § 53.30(a).

The Commission has retained the phrase "extraordinary costs" in § 53.13(a) and § 53.30(a)(5) of the final rule. Use of the "extraordinary costs" standard is necessary to reflect the Congressional intent that Federal interim storage should be utilized only in exceptional circumstances. However, the Commission has revised § 53.30(a)(5) to allow for consideration of not only extraordinary costs related to the "amount of additional storage capacity needed" or "the time for which additional storage capacity is needed," but also other extraordinary costs that are clearly unreasonable when compared with the costs of Federal interim storage. The Commission has added a provision to § 53.13(a) requiring the submittal of information on the costs of providing the necessary additional capacity and the time for which the capacity is needed. Section 53.12(c) has also been revised to provide for the submission of any information, in addition to that specified, the Commission should consider in making its determination.

The last comment received from the industry on the contents of the request required by § 53.13 concerns clarification of the information relating to legal and institutional impediments. Section 53.13(a) of the proposed rule required information on "local or State laws limiting or preventing the timely expansion or addition of storage capacity or transshipment." Several industry commenters recommended the addition of "state or local regulatory actions." One commenter recommended the addition of "preexisting contractual agreements."

Another suggested the addition of "Commitments made by a utility to a public service Commission or local commenters." This would reflect commitments on the storage of spent fuel made by a utility during the siting

full core reserve, the Commission acknowledges that various sections of the Nuclear Waste Policy Act refer to the need for that capacity at the reactor for which the determination is requested. Nevertheless, the Commission believes that this does not preclude it from making a reasonable generic finding that full core reserve is necessary for continued, orderly operation. The Commission's finding is based on the possibility that a reactor would be required to shut down and discharge its fuel, as well as the financial consequences that would flow from the unavailability of full core reserve. The Commission finds that even if the probability of needing full core reserve differs from reactor to reactor and may be low in some cases, the possibility that full core reserve would be needed, combined with the substantial costs that would be incurred if full core reserve were not available when needed, would preclude the Commission from determining that the "maintenance of such capability [full core reserve] is not necessary for the continued orderly operation of such reactor." Nuclear Waste Policy Act of 1982, section 135(b)(2). The Commission would also note that problems such as pipe cracking and steam generator repair raise the overall importance of maintaining full core reserve discharge capability. Estimates cited in a recent DOE study [6] indicate that if full core reserve is required and not available, an additional 50 to 90 days of reactor shutdown would be experienced. A 1979 study,[7] citing data developed by the Energy Information Administration, estimated that the cost of replacement power for a reactor that was shut down would range from $320,000 to $556,000 per day. Adjusting these estimates to 1982 average costs for coal, oil, and gas, a range of $360,000 to $650,000 per day is a reasonable estimate of the cost of replacement power for a 1000 Mwe nuclear plant at 60% capacity factor. Therefore, the potential exists for substantial costs resulting from the absence of full core reserve capacity. In addition to the potentially high costs of operating without full core reserve, one statistical analysis of full core removals from nuclear power plants indicates that a full core discharge would be expected to occur about once every six years at any given nuclear power plant, and could occur as often as once every three years.[8] The Commission's generic

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[6] U.S. Department of Energy, *Spent Fuel Storage Requirements*, DOE/RL-83-1 at 12 (January, 1983).

[7] *Supra*. Note 4.

[8] Pickard Lowe, and Garrick, "Full Core Removal Study" (1979).

finding that full core reserve is necessary for continued, orderly operation of a nuclear power plant, solely for purposes of the 10 CFR Part 53 determination, allows the Commission to concentrate its staff resources on evaluating the critical issues of the feasibility of storage alternatives and the diligence of the person making the request in pursuing those alternatives, rather than speculating on whether full core reserve is necessary in an individual case. The anticipated loss of full core reserve discharge capability is one element of eligibility to file a request for a Commission determination under Part 53. In addition, the Part 53 criteria on feasibility and diligence provide guidance to a utility on whether it will be eligible for Federal interim storage. In effect, as suggested by one commenter, the Commission has limited the full core reserve finding to only those plants that have a possibility of satisfying the eligibility criteria for Federal interim storage. As stated previously, the generic finding does not require a reactor licensee to maintain a full core reserve.

The Commission does not believe that it is necessary, or advisable, to defer its decision on full core reserve. The Commission's determination on full core reserve is for a very limited purpose, and there is sufficient data to support this determination. Furthermore, Section 135(g) of the Nuclear Waste Policy Act requires the Commission to consider the full core reserve issue at this time, and the proposed rule has afforded a full opportunity for public comment on this issue.

In view of the Commission's generic finding that full core reserve is necessary for the continued orderly operation of a nuclear power plant, and the basis for that finding as discussed previously, the incorporation of such factors as source and cost of replacement power into § 53.30(b) is unnecessary.

The Commission is aware that various reasons may call for the maintenance of more than one full core reserve at a multireactor site. Therefore, § 53.30(c) of the proposed rule has been retained to allow the Commission to consider, and to find, that more than one full core reserve is necessary at a multireactor site. In addition, § 53.12(c) has been revised to provide for information to be submitted to this point. Finally, because the primary purpose of the spent fuel pool is for the storage of spent fuel, the Commission is not making any allowance for storage space that has been taken up by anything other than spent fuel.

7. Alternatives to Federal Interim Storage

Two major issues were raised by the comments submitted on spent fuel storage alternatives. The first concerns the scope of the alternatives included under "any other technologies that have been approved by the Commission." Proposed § 53.13(c)(5). The second issue involves whether the Commission should treat some alternatives as preferable to others.

The criteria contained in proposed § 53.30 relating to the feasibility of implementing alternatives to Federal interim storage, and diligence in pursuing these alternatives, apply to the alternatives set forth in proposed § 53.13(c). These alternatives, derived from Section 135 of the Nuclear Waste policy Act, follow:

(1) Expansion of existing storage facilities, including high-density fuel storage racks or fuel rod compaction;

(2) Construction of new or additional spent nuclear fuel storage facilities at the site of any civilian nuclear power reactor operated by such person;

(3) Acquisition of modular or mobile spent nuclear fuel storage equipment, including spent nuclear fuel storage casks, for use at the site of any civilian nuclear power reactor operated by such person;

(4) Transshipment of spent nuclear fuel to the site of another civilian nuclear power reactor within the same utility system; and

(5) Such other technologies as may be approved by the Commission.

The public interest group and State government commenters asserted that the alternatives required to be examined are not confined to those specifically identified in section 135(b)(1)(B) of the Nuclear Waste Policy Act, but also include any new and promising alternatives. This would include any storage technology that may be favorable even if not already licensed by the Commission. According to one commenter, this would encourage creativity in developing alternatives and also avoid reliance on the pace of the Commission's licensing process for new technologies.

In contrast, the industry commenters stated that utilities should be required to pursue only those spent fuel storage alternatives that have already been licensed by the Commission or, at the very least, for which a license application has been submitted. According to this view, as new alternatives are licensed, they can be added to the technologies that a utility would be required to consider as alternatives. In addition, a few industry commenters requested that the Commission clarify whether a utility must pursue all of the alternatives specified in the proposed rule, even though some, if not all, of the alternatives may not be feasible for certain utilities. A related comment submitted by one utility advocated that the Commission eliminate in advance some alternatives from consideration as being too expensive to implement.

The Commission does not believe that Congress intended to limit the pursuit of alternatives to those already licensed by the Commission, as was suggested by the various industry comments. Not only does the Nuclear Waste Policy Act specifically require consideration of storage technologies that have not yet been licensed by the Commission—fuel rod compaction and dry storage casks—but, in addition, the legislative history of section 135 of the Act is replete with references to the utilities' investigation of technologies that are, as of yet, unlicensed. For example, Senator Simpson, in describing the national policy that the Act would establish for the interim storage of spent fuel, stated:

> Under this policy, the utility operators of nuclear power plants bear the primary responsibility for the interim storage of spent fuel at the sites of their nuclear plants. This places a significant, but appropriate, burden on the utilities to do everything possible to assure sufficient onsite storage capacity through a variety of measures specified in the legislation. These measures include reracking, transshipment of spent fuel between reactors within the same utility system, and the use of new technologies such as dry storage and the use of storage casks.
> 128 Cong. Rec. S4157 (daily ed., April 28, 1982)

Representative Gejdenson, one of the authors of the spent fuel alternatives provisions in the House version of the Act, highlighted the investigation of dry storage as an alternative to Federal interim storage by stating:

> Documentation from the Office of Technology assessment, the Department of Energy, the Nuclear Regulatory Commission, and the European Nuclear Community clearly indicate that alternative technologies, such as dry storage casks, dry caisson storage, and concrete silo storage offer effective, safe, and inexpensive solutions to the interim storage problems. I feel confident that interim onsite storage will be in use at many nuclear reactors lacking sufficient pool storage.
> 128 Cong. Rec. H8178 (daily ed., September 30, 1982).

Therefore, in making its determination, the Commission will evaluate the feasibility of both licensed and unlicensed alternatives as required by section 135(b)(1)(B) of the NWPA, and will require utilities to be diligent in their pursuit of those alternatives. As new technologies are approved by the Commission for use at the sites of civilian nuclear power reactors, utilities will be required to investigate these alternatives as well, as provided in section 135(g) of the NWPA. Rather than have two different sets of alternatives, the Commission has combined the requirements of these two Sections of the Act in § 53.13(c) of the final rule. However, it is clear from the legislative history that Congress required the investigation of only those spent fuel storage alternatives that are technologically feasible within the relatively near future. This would roughly correspond to a 1986–87 time frame and, according to congressional debates, would include fuel rod compaction and dry storage modular techniques. Utilities are not presently required to explore alternatives whose technical feasibility cannot be demonstrated until some time in the distant future.

In response to the utility comment requesting clarification on whether it must pursue all alternatives, even though some may be infeasible, the Commission emphasizes that, although a utility must satisfy the Commission's criteria on feasibility and diligence for the alternatives currently within the scope of Part 53, it does not have to pursue an alternative that is infeasible. However, the utility must demonstrate that it has considered each alternative and must provide a rationale, based on the criteria in § 53.30, as to why a particular alternative is infeasible. Owing to the number of factors that influence whether an alternative is feasible, as well as the judgment involved in making this decision, the Commission does not believe it would be consistent with Congressional intent to eliminate any alternatives in advance.

The second major area of concern was the assertion by public interest group and State government commenters that the Commission should give preference to on-site storage alternatives in making its determination. In support, these commenters cited the legislative history of the Nuclear Waste Policy Act to the effect that on-site storage of spent fuel should be encouraged and that transportation of spent fuel should be minimized.

The Commission does not have any authority under Subtitle B of the Nuclear Waste Policy Act to establish priorities for the pursuit of spent fuel storage alternatives in the context of a Part 53 determination, as recommended by the public interest group commenters. The authority provided by section 135(b) of the Act requires the Commission to determine the feasibility of a utility's implementing each of a broad range of alternatives. If the implementation of one or more alternatives is feasible, the utility is not eligible to participate in the Federal interim storage program. The choice of which alternative to Federal interim storage a utility should then pursue will be decided elsewhere. The Commission notes that an earlier version of the proposed legislation, H.R. 6159, did contain a provision requiring a utility to be diligent in pursuing alternatives on a priority basis. However, this provision was not included in the final version of the Bill as approved by the House of Representatives. Thus, any preference expressed in the Act for on-site storage does not apply in the context of a Part 53 determination.

8. Diligence

In order for a utility to be eligible for Federal interim storage, section 135(b) of NWPA requires the Commission to make two affirmative findings:

1. A person owning and operating a civilian nuclear power reactor cannot reasonably provide adequate spent nuclear fuel storage capacity at the reactor site, or at the site of any other reactor operated by that person, when needed to ensure the continued orderly operation of the reactor; and
2. The person owning and operating the reactor is "diligently pursuing licensed alternatives to the use of Federal storage capacity" for the storage of spent nuclear fuel expected to be generated in the future.

Under proposed § 53.30(d), to determine whether the requesting person has been diligently pursuing licensed alternatives to the Federal storage of spent nuclear fuel, the Commission will consider whether the person has initiated timely action either to provide the necessary storage capacity or to evaluate the feasibility of providing the necessary storage capacity. Although license applications are one example of these actions, the Commission will also consider the preparation of reports or studies that thoroughly investigate the technical feasibility, costs, and public health and safety aspects of alternative storage options.

A number of State government and public interest group commenters did not believe that the Commission's proposed criteria provided sufficient detail to guide the Commission or a utility in determining what would constitute "diligent pursuit" of licensed alternatives. In addition, one of these commenters challenged the authority of the commission to consider anything other than license applications in making the diligence finding. The rationale for this later point was the definition of diligence contained in the report of the House Committee on Interior and Insular Affairs:

> The committee considers diligent pursuit of alternatives to be represented by application for and processing of licenses or other authorizations necessary to (sic) acquisition of storage capacity * * * H.R. Rep. No. 125, 97th Cong. 2d. Sess. 62 (1982).

Therefore, this commenter argued that the Commission cannot consider reports or studies as sufficient in lieu of a license application.

Although most of these commenters did not offer recommendations on how the Commission could provide more detailed criteria, one commenter did propose an alternative scheme for addressing the diligence issue. Comment Letter No. 8. The proposal would require all utilities that do not have sufficient on-site storage capacity for accommodating all the spent fuel to be generated during the term of the License to file a report, updated annually, containing information on when full core reserve will be lost, the actions that the utility has taken to avoid the need for Federal interim storage, the rationale for rejecting storage alternatives, the amount of time required to implement any alternatives that are still under consideration, and any actions that the utility has taken to maximize the efficiency of fuel usage and to prevent fuel damage. According to the commenter, this would allow the Commission's diligence finding to be "based on historical information, which would be far more reliable than the utility's *ad hoc* justification developed under pressure of impending loss of storage capacity." Comment Letter No. 8 at 4.

In addition to the reporting requirements, the commenter's proposal would require a utility to file either a license application for an alternative to Federal storage within 6 months of determining that it would lose full core reserve, or a justification for its decision not to file a license application. This justification would have to be accompanied by a plan with a specific timetable for the development and implementation of a license application. A utility would not be considered diligent unless it had filed an application for an alternative within one year after determining that it would lose full core reserve, unless the utility demonstrated that all alternatives to Federal interim storage are physically impossible or economically impracticable. Finally, the proposal included a provision that a utility could not be considered diligent if it had failed reasonably to maximize the efficiency of its fuel usage or because the fuel suffered damage that could reasonably have been avoided. A number of other commenters also recommended that the Commission consider the history of fuel management, pool design and maintenance. One commenter suggested that the Commission fine utilities with a record of improper management in these areas. A State commenter suggested that the Commission analyze utility leadership and cooperation in utility ownership or pooled ownership of casks for transporting and storing spent fuel.

The Commission believes that the circumstances surrounding the Federal interim storage program do not warrant the imposition of the extensive reporting requirements suggested in the public comment letter. The primary resonsibility for providing interim storage of spent fuel rests with the utilities. In light of the relatively few utilities that may be compelled to seek Federal storage, it would not be productive for the Commission to impose a blanket reporting requirement on every utility that may not have sufficient on-site storage capacity for the spent fuel to be generated during the term of the operating license. Furthermore, the Commission would note that the proposed rule requires a utility that desires eligibility for the Federal interim storage program to submit essentially the same information as sugested by the commenter. However, the Commission does find that portions of the proposal dealing with submission of information on the history of reactor refueling and of actions intended to provide additional spent nuclear fuel storage are an improvement over the information request format in the proposed rule and accordingly, has revised § 53.12 to reflect this. In addition, the Commission agrees with the commenters that studies or reports on spent fuel stroage alternatives alone would not be sufficient to constitute evidence of diligence. This is represented by § 53.30(d) of the final rule. A person making a request will not be expected to have a license application pending for each alternative to Federal interim storage. However, in order to find that the person has been diligently pursuing alternatives, the Commission would expect that an application for at least one alternative would exist, along with a plan or program for evaluating the feasibility of alternatives, and studies that form the basis for demonstrating why certain alternatives have not been pursued.

Finally, the Commission does not believe that it is within its authority under the Nuclear Waste Policy Act to factor fuel handling and management or pool design considerations into the diligence determination, much less to penalize a utility for poor management in these areas in the context of a Part 53 determination. The text of Section 135(b) of the Act, and the legislative history cited previously, indicate that diligence relates only to the pursuit of storage alternatives and not to any considerations of fuel management or pool design.

9. Feasibility

In addition to diligence, eligibility for the Federal interim storage program is dependent on the Commission's determination that the person owning or operating a civilian nuclear power reactor cannot reasonably provide adequate spent fuel storage capacity at the reactor site, or at the site of any other reactor operated by that person, when needed to ensure the continued orderly operation of the reactor. This determination is dependent on feasibility, taking into account the economic, technical, regulatory, and public health and safety factors of providing adequate storage capacity through various storage alternatives. Proposed § 53.30 establishes several constraints on the feasibility of implementing storage alternatives that the Commission will consider in making the adequate capacity determination.

Comments on these criteria were submitted by public interest groups and the nuclear industry. Although most of these comments were addressed to specific criteria, a few commenters addressed the criteria generally. For example, one utility was concerned that the criteria could be so restrictive as to unjustly limit the usefulness of the Federal interim storage program. The opposite viewpoint was expressed by a public interest group commenter, who felt that the criteria were not specific enough to determine when a utility would qualify for the Federal storage program. In response, the Commission emphasizes that, first, the clear Congressional intent was for the interim Federal storage program to provide only a limited amount of storage capacity on an exceptional basis to utilities that are unable to reasonably provide their own storage capacity in time to ensure the continued orderly operation of the reactor. Therefore, the Commission does not believe that the criteria are too restrictive. Second, in order to provide the flexibility necessary to address a potentially wide range of individual storage capacity situations and to apply the broad factors cited in section 135(g) of the Nuclear Waste Policy Act, the criteria must necessarily be somewhat broad. In §53.30(a), the Commission has sought to strike a proper balance between attempting to quantify every possible situation that would render an alternative unreasonable and merely restating the broad criteria of section 135(g) of the Act. The Commission notes that it is fully cognizant of the Congressional intent that the Federal interim storage program be utilized only as a last resort, and will apply the criteria of § 53.30(a) accordingly.

In terms of comments on individual criteria, a State asked if the term "site" in § 53.30(a)(1) is a utility site or a Federal site. In the context of its use, the Commission believes it is clearly a reactor site and has modified the rule accordingly. A public interest group commenter recommended that proposed § 53.30(a)(3), on the inability to obtain the necessary shipping or storage equipment, be deleted. The commenter, characterizing this consideration as a "possible justification for use of a federal AFR facility," reasoned that if the Federal government could provide shipping from, or storage at, a particular site, the utility could have done so as well. Comment Letter No. 8, at 5. Therefore, the shipping or storage alternative could not be infeasible because of the lack of shipping or storage equipment.

The Commission's intent was to allow for consideration of those situations where a utility, through no fault of its own, could not utilize a particular alternative because of the physical unavailability of materials or equipment within the time frame necessary. This provision must be viewed in the context of the numerous alternatives to Federal storage. There may be cases where an alternative cannot be implemented because of the unavoidable shortage of materials and equipment. This would then shift the focus to other alternatives. To qualify for the Federal interim storage program, the utility would still be required to demonstrate that all other alternatives are infeasible. Although it is anticipated that the lack of equipment will rarely be a determining factor, the Commission does not want to foreclose this possibility from consideration. In order to delete the emphasis of the provision on any particular storage alternatives, the Commission has reworded § 53.30(a)(3). Under the interim Federal storage program established by the Nuclear Waste Policy

Act, the Commission's responsibility is to determine whether it is infeasible for the utility to implement all storage alternatives owing to economic, technical, regulatory, or public health and safety reasons. If this is demonstrated, and the utility is diligent in pursuing alternatives, it is the Federal Government's responsibility to provide storage.

A number of comments addressed the criterion in proposed § 53.30(a)(7) which provides for consideration of legal impediments to the implementation of an alternative, such as State and local laws or preexisting contractual agreements that cannot be alleviated in a timely manner. A commenter, representing several nuclear utilities, requested that this provision be clarified so as not to encourage or endorse enactment or enforcement of State and local laws involving matters committed exclusively to the NRC, DOT, or other Federal agencies. This commenter recommended the substitution of the following provision for proposed § 53.30(a)(7):

> Legal impediments to the implementation of an alternative, such as state and local laws pertaining to matters within the jurisdiction of those levels of government, which are valid and enforceable or though not valid, cannot reasonably be invalidated or enforcement enjoined in a timely manner.
>
> Comment letter No. 23, at 5.

A second commenter also asked for clarification of this provision. In fact, the commenter recommended the elimination of the provision because of the concern that State and local laws would be enacted simply to require the fuel to be shipped offsite and into Federal storage. In the commenter's opinion, ". . . State and local laws such as 'blanket' prohibitions that are inconsistent with Federal laws (e.g., interstate commerce laws) might be afforded an inappropriate statute" by proposed § 53.30(a)(7). Comment letter No. 16, at 2.

The intent behind proposed § 53.30(a)(7) was to allow the Commission to consider any State or local laws (statutes, ordinances, administrative regulations) or preexisting contractual arrangements that might limit the implementation of a storage alternative. In the course of evaluating the impact of a State or local law, the Commission necessarily would have to inquire into the nature and extent of impact, including the apparent validity and enforceability of the law in question, and whether the utility has taken reasonable and timely steps to identify and alleviate constraints imposed by State or local laws. The suggested revision of § 53.30(a)(7) accomplishes the same result, but clarifies the nature of legal impediments that might affect a utility's eligibility for Federal interim storage. Accordingly, the Commission has adopted the suggested revision.

In response to the commenter's concern, the Commission would note that it is a possibility that a particular alternative may not be feasible, at least for a given time period, because of a State or local law. Therefore, the Commission criteria should take this possibility into account. The Commission does not believe that such a criterion will encourage the enactment of State or local laws prohibiting the transportation of spent fuel. This is particularly true in light of the U.S. Court of Appeals for the Second Circuit decision in *City of New York* v. *U.S. Department of Transportation*, 715 F. 2d 732 (2d Cir. 1983). The Circuit Court upheld the validity of the DOT routing regulations for the transportation of radioactive materials, which preempt all inconsistent State and local regulations.

A number of nuclear industry commenters suggested that the Commission delete the term "extraordinary" from proposed § 53.30(a)(5), which allowed the Commission to consider the costs of implementation of a particular alternative. These commenters argued that, in evaluating the economics of an alternative, the Commission only need consider clearly unreasonable costs. In light of the clear Congressional intent that Federal interim storage be a last resort option, the Commission is retaining the "extraordinary costs" terminology as an appropriate expression of that Congressional intent. Another industry commenter suggested that the definition of "extraordinary costs" must include consideration of the facility's ability to recover the costs associated with implementation of an alternative. The Commission disagrees. In evaluating the feasibility of an alternative from an economic standpoint, the Commission's primary concern is whether the implementation involves "extraordinary costs . . . that are clearly unreasonable . . ." § 53.30(a)(5). Although the Commission will not foreclose consideration of whether the utility can recover the costs of implementation, the Commission does not believe that the issue of cost recovery should be a necessary or determining factor in evaluating the feasibility of an alternative. A State commenter suggested that only unique local economic considerations or unique orderly operations scenarios be considered in the Commission's determination regarding feasibility. Although it is unclear exactly what the commenter means by "unique local economic considerations or unique orderly operations scenarios," the Commission believes that the criteria contained in the final rule, including the consideration of the "extraordinary costs of implementation" (§ 53.30(a)(5)), are appropriate statements of the types of factors that may make an alternative to Federal interim storage unreasonable, and are a consistent expression of the Congressional intent that such storage be a last resort option.

Several nuclear industry commenters recommend that the Commission delete any references to "timeliness" from the proposed criteria in § 53.30(d) for determining diligence. These commenters believe that diligence and good faith are the key factors for the Commission's determination in § 53.30(d), and that words and phrases such as "timely", "as early as possible", and "prompt development", should be eliminated. As expressed by one commenter, "while the utility is required to demonstrate diligent and good faith efforts, such efforts may simply be untimely (or unproductive) through no fault of the utility." Comment letter No. 15, at 6.

Although the Commission does recognize that there may be cases where a utility's efforts are untimely through no fault of its own, one factor that must be considered in evaluating diligence is whether the utility has explored storage alternatives in a timely manner. Timeliness is a key consideration in ascertaining diligence. Therefore, no revision of the rule is warranted based on these comments.

A State commenter recommended that § 53.30(d)(3), which establishes one of the criteria to guide the Commission's "diligence" determination under § 53.27(a)(2), be revised to read:

> The timely implementation of a spent nuclear fuel storage program which has utilized all available options for storage of spent fuel at the reactor, or within the utility, if necessary, taking into account technical, economic, regulatory, and public health and safety factors, and that includes the prompt development of feasible alternatives to Federal storage.

The Commission believes that the criteria contained in § 53.30(d) already address the concerns expressed in the above comment.

10. National Environmental Policy Act (NEPA).

The Commission received two comments on National Environmental Policy Act issues. One State sought clarification of whether issuance of a determination under Part 53 may be subject to NEPA. A public interest group stated that the Commission should consider itself bound to operate within all of the provisions of NEPA in regard to all its decisions concerning Federal interim storage. In response, the Commission believes that the environmental appraisal contained in the draft Regulatory Analysis for the proposed rule adequately addresses these comments. A summary of that appraisal appears in the Commission's Finding of No Significant Impact which follows in this preamble.

11. Miscellaneous

One commenter raised several concerns over the use of the Idaho National Engineering Laboratory as a Federal interim storage site. The Commission notes that the use of a specific site for Federal storage is not within the scope of the Part 53 rulemaking or the determination required under section 135(b) of the Nuclear Waste Policy Act. All comments on specific storage sites must be addressed in connection with the implementation of section 135(a), (c), and (d) of the Act.

A nuclear industry commenter requested that the Commission clarify proposed § 53.1 to indicate that the pursuit of storage alternatives is only a "stop gap" approach, necessary only until such time as the final repositories are established. The Commission believes that the reference in proposed § 53.1 to section 135(b) of the Nuclear Waste Policy Act appropriately limits the application of the rule.

The same commenter requested clarification on which 10 CFR Part 170 fee category a request for a determination would fall. The Commission intends to assess fees for Part 53 determinations as "special projects" pursuant to 10 CFR 170.31, "Schedule of Fees for Materials Licenses and Other Regulatory Services." Charges will be separately determined, taking into account the professional manpower required to conduct the review multiplied by the applicable cost per staff-year, plus any appropriate costs incurred for support services. Once the Commission has gained some experience with the processing of Part 53 determination requests, it will determine whether a standard fee for such services should be established.

III. Section-by-Section Revisions

1. Section 53.5

This section has been revised to reflect the current OMB regulations on the implementation of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). Section 1320.7(u) of 5 CFR Part 1320 creates an irrebuttable presumption that any information collection requirements contained in a rule of general applicability will involve 10 or more persons and therefore must be reviewed and approved by OMB. Accordingly, the Commisison has submitted the final rule to OMB for clearance.

2. Section 53.6

The Commission has added an exemption provision as § 53.6 of the final rule. Because many of the requirements of the rule, including the spent nuclear fuel storage alternatives, which must be considered before a determination can be made as to the need for Federal interim storage, are taken directly from the Nuclear Waste Policy Act of 1982, no exemptions can be given to their provisions. The exemption provision is, therefore, not expected to be put to much use. It is included to give the Commission the flexibility to implement the provisions of the Act in ways not now contemplated by the regulations in 10 CFR Part 53.

3. Section 53.11

Section 53.11(a) has been revised to require 10 copies of a request instead of the 20 copies specified in the proposed rule. Ten copies are adequate to meet the NRC need to conduct an expedited review of a request. Section 53.11(b) has been revised to allow the filing of a request for a determination at any time that a need can be demonstrated, up to the June 30, 1989 filing deadline. An exception to the filing deadline may be granted if the request is likely to be processed prior to January 1, 1990 and the person making the request has shown good cause for the failure to file on time. Section 53.11(c) has been revised to allow for a 30-day public comment period and for the NRC transmittal of a copy of the request to DOE Office of Civilian Radioactive Waste Management. Section 53.11(d) has been revised to specify the basis on which the fee for a determination request will be assessed. Section 53.11(e) has been added to allow the Commission to suspend the acceptance for filing of requests if the total amount of Federal interim storage authorized by section 135 of the Nuclear Waste Policy Act has been fully contracted for.

4. Section 53.12:

The format of § 53.12 has been changed. In addition, § 53.12(c) has been revised to require the submission of additional information on the fueling/refueling cycle of the reactor, the amount and location of any fuel stored offsite, and the necessity of maintaining more than one full core reserve at multireactor sites. Finally, § 53.12(c)(9) has been added to allow the submission of other information which the Commission should consider in making its determination.

5. Section 53.13:

The title of this section has been changed to "Contents of a request: alternatives." Section 53.13(a) has been revised to specify that the analysis of spent fuel alternatives is keyed to constraints that would make the implementation of an alternative "unreasonable," rather than those that would "prevent" their implementation. Section 53.13(a)(5) has been revised to include regulatory actions and preexisting agreements. Section 53.13(a)(8) has been revised to eliminate the word "consumers." Although the Commission will consider who bears the costs of implementation, the key consideration is the type and amount of the cost. Section 53.13(a)(8) has also been revised to include information on the costs of providing the necessary additional capacity and the time for which the capacity is needed. Section 53.13(b) has been placed into a new format. Section 53.13(c) now contains the alternatives formerly specified in § 53.27(a)(2).

6. Section 53.15:

Paragraph (a) of this section has been revised to permit the person submitting the request to withdraw the request up to the time of the intial determination without asking permission of the Commission or EDO.

7. Section 53.27:

The alternatives formerly listed in § 53.27(a)(2) are now found in § 53.13(c).

8. Section 53.30:

Section 53.30(a) has been revised to focus the Commission's analysis of the feasibility of alternatives on factors that would make an alternative "unreasonable" as opposed to "impractical." Section 53.30(a)(5) has been revised to include, in the consideration of extraordinary costs, the comparative cost of Federal interim storage. Section 53.30(a)(7) has been revised to include regulatory actions and preexisting agreements.

IV. The Final Rule

1. Subpart A—General Provisions

Sections 53.1 through 53.6 address a number of general issues, including purpose and scope of the rule, definitions, communications with the Commission, interpretations of the rule, and a new general exemption provision. The rule applies to all persons owning or operating domestic civilian nuclear power reactors who submit a request for a Commission determination under section 135(b) of the Nuclear Waste Policy Act. This determination consists of a decision by the Commission as to whether adequate spent nuclear fuel storage capacity to ensure the continued orderly operation of a particular reactor cannot reasonably be provided in a timely manner by the person owning or operating that reactor.

2. Subpart B—Request for a Commission Determination

Subpart B specifies the procedures that must be followed and the information that must be submitted by a person seeking a Commission determination. The final rule requires the submission of information on spent nuclear fuel storage capacity and need, feasible storage alternatives, and the diligence of the person requesting the determination in pursuing alternatives. This information will enable the Commission to determine—

- Whether additional capacity is needed, in what amount, and in what time frame, and
- Whether it is practical for the person making the request to implement alternatives to Federal interim storage in light of technical, economic, regulatory, and public health and safety constraints.

Subpart B also sets forth procedures related to the filing and distribution of a request for a Commission determination. These procedures provide for publication of notice of receipt of a request in the **Federal Register** to inform the public that Commission action on the request is pending and for a 30-day public comment period. The solicitation of comments is for the purpose of generating more complete information for Commission review. Such a solicitation is an optional procedure that is not required by either the Atomic Energy Act or the Nuclear Waste Policy Act. Consequently, a detailed comment analysis need not be prepared. However, the Commission will consider all comments in making its determination, and will address in the determination any significant comments received.

The making of a Commission determination under section 135(b) of the Nuclear Waste Policy Act is not a "proceeding . . . for the granting, suspending, revoking, or amending of any license or construction permit, or application to transfer control . . . ," pursuant to section 189a. of the Atomic Energy Act. Accordingly, there is no opportunity for a hearing in connection with a request for a Commission determination. Similarly, there is no right to petition the Commission for review of an initial determination of the Executive Director for Operations under Subpart C of the rule. Of course, if a licensee seeks permission to implement a licensed alternative to Federal interim storage of spent fuel, an opportunity for a hearing would be available in that licensing proceeding. Although some of the same facts might be in issue, a Commission determination under section 135(b) would be entirely separate from the decision of the presiding officer in a licensing proceeding. In addition, the final rule should not be construed as expressing any Commission position on the feasibility of a particular storage technology. A licensee's use of a specific storage technology will require Commission evaluation and approval.

3. Subpart C—Issuance of a Commission Determination

Subpart C establishes the criteria and standards that the Commission will use to make the statutory determinations—

- That adequate storage capacity cannot reasonably be provided in a timely manner, and
- That the person requesting the determination has been diligently pursuing licensed alternatives to the use of Federal storage capacity.

In determining the ability of the requesting person to reasonably provide adequate storage capacity, the Commission will consider any technical, economic, regulatory, or public health and safety factors that would constrain implementation of alternatives to Federal storage. Although it is not possible to anticipate all the constraints that could affect the ability of a reactor owner or operator to implement a spent fuel storage alternative, these constraints could include such factors as structural limitations; inability to meet the Commission's regulatory requirements due to factors beyond the licensee's control; the extent to which implementation would disrupt operation of the reactor; unavailability of necessary materials or equipment; legal impediments; unusual licensing delays; the time required for licensing, design, and construction; extraordinary costs; and consideration of offsite and occupational radiation exposure. Depending on the particular facts, a single factor or a combination of factors could make implementation of a given alternative unreasonable. While it is not anticipated that either occupational or offsite public health and safety will be a determining factor as long as the applicable Commission regulations are met, the criteria do allow for consideration of unusual circumstances where radiation exposure is unreasonably out of proportion to the amount of additional storage capacity needed or the time period for which it is needed.

In determining whether the requesting person has been diligently pursuing licensed alternatives to the Federal storage of spent nuclear fuel, the Commission will consider whether the person has initiated timely action either to provide the necessary storage capacity or to evaluate the feasibility of providing the necessary storage capacity. Although license applications are one example of these actions, the preparation of reports or studies that thoroughly investigate the technical feasibility, costs, and public health and safety aspects of alternative storage options will also be considered by the Commission. A person making a request will not be expected to have a license application pending for each alternative to Federal interim storage. However, in order to find that the person has been diligently pursuing alternatives, the Commission does expect that an application for at least one alternative would exist, along with a plan or program for evaluating the feasibility alternatives, and studies that form the basis for demonstrating why certain alternatives have not been pursued.

Section 135(g) of the Act requires the Commission's criteria to ensure the maintenance of full core reserve storage capability at the site of the reactor unless the Commission determines that such capability is not necessary for the continued orderly operation of the reactor. Commission policy has been to permit continued operation at licensed reactor facilities where less than a full core reserve is maintained because such operation does not constitute an undue risk to the health and safety of the public. While a full core reserve capability is not an NRC safety requirement, the Commission has recognized that the maintenance of a full core reserve would be a prudent management practice on the part of the reactor operator.

Full core reserve would be needed to prevent extended reactor outages in the event a core had to be discharged in order to inspect the reactor pressure vessel or to conduct routine and unscheduled maintenance. Although a reactor could be quickly and safely shut down without full core reserve, if the core had to be discharged, the reactor would have to remain shut down while arrangements for shipping and storage were made and executed. During this time, the utility would have to purchase supplemental power at substantial additional cost to its customers (See previous discussion under "Responses to Public Comments on the Proposed Rule," "Full Core Reserve."). The Commission finds that even if the probability of needing full core reserve may differ from reactor to reactor and may be low in some cases, the possibility that full core reserve would be needed, combined with the substantial costs that would be incurred if full core reserve were not available when needed, would preclude the Commission from determining that the "maintenance of such capability [full core reserve] is not necessary for the continued orderly operation of such reactor." Nuclear Waste Policy Act of 1982, section 135(b)(2). The Commission also notes that problems such as pipe cracking and steam generator repair could raise the overall importance of maintaining full core reserve discharge capability.

The Commission interprets "continued, orderly operation" to mean the avoidance of extended reactor shut-down due to lack of spent fuel storage capacity. The Commission considers the likelihood of needing full core reserve, and the resulting costs from not having that discharge capability, to be inconsistent with continued orderly operation. Therefore, the Commission has made a generic finding that, for the purposes of a determination under this part, full core reserve is necessary for the continued orderly operation of the reactor. The legislative history of the Nuclear Waste Policy Act suggests that the maintenance of full core reserve is closely related to the concept of continued, orderly operation. As first introduced in the Senate, the bill provided for a determination of whether adequate storage capacity could be provided to ensure continued, orderly operation "through the maintenance of a full core reserve capability." S. 1662, 97 Cong., 2d Sess., section 302(a), 128 Cong. Rec. S4139, S4141 (daily ed., April 28, 1982). This language was later changed to that now found in the Waste Act, which gives the Commission the flexibility to examine whether full core reserve is needed for continued, orderly operation. In this context, the Commission believes that a generic finding that full core reserve is necessary for continued, orderly operation is consistent with Congressional intent. The generic finding contained in § 53.30(b) relates solely to the time when Federal interim storage may be needed. The generic finding does not require a licensee to maintain a full core reserve.

Where two or more reactors share a particular site, the maintenance of a single full core reserve capability should normally be sufficient to ensure continued orderly operation. However, the person requesting the determination has the opportunity to demonstrate that special circumstances require the maintenance of more than one full core reserve at the site. The special circumstances could include the inability to utilize available storage space for some reason; for example, incompatibility between the storage pool and the fuel type.

Because a license is not involved and the determination is based primarily on matters within the technical competence of its staff, the Commission has provided in Subpart C that the Executive Director for Operations, or his or her designee, shall make the initial determination. Section 1.40 of 10 CFR Part 1 has been revised to reflect this delegation. Redelegation beyond the office director level is prohibited. However, the initial determination is subject to Commission review, at the Commission's discretion. The final determination must be made within 6 months of the receipt of the request.

V. Other Requirements

Finding of No Significant Environmental Impact

1. This final rule will establish procedures and criteria for a Commission determination under section 135(b) of the Nuclear Waste Policy Act of 1982 that a person owning and operating a civilian nuclear power reactor cannot reasonably provide adequate spent nuclear fuel storage capacity at the reactor site when needed to ensure the continued orderly operation of the reactor.

2. The Commission has determined under the National Environmental Policy Act of 1979, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that promulgation of this final rule is not a major Federal action significantly affecting the quality of the human environment, and, therefore, an environmental impact statement is not required.

3. The Commission activities under this aspect of the Nuclear Waste Policy Act of 1982 consist of the establishment of procedures and criteria for making the determination required by the Act, and the determinations themselves. Neither of these activities has an environmental effect. Any environmental impacts that might ultimately occur result from the decision of the Secretary of Energy to enter into a specific contract with a utility, not from the prior Commission determination.

4. An environmental impact statement need not be prepared in connection with this rulemaking action because promulgation of the final rule is not a major Federal action significantly affecting the quality of the human environment within the meaning of NEPA. The final rule will establish procedures and criteria for a Commission determination under section 135(b) of the Nuclear Waste Policy Act of 1982 that a person owning and operating a civilian nuclear power reactor cannot reasonably provide adequate spent nuclear fuel storage capacity at the reactor site when needed to ensure the continued orderly operation of the reactor. The adoption of such procedures and criteria by promulgation of a final rule does not have an environmental effect.

The making of a Commission determination in accordance with these procedures and criteria is also without environmental effect. The sole purpose of a Commission determination is to provide assurance, in a specific factual context, that the person generating or owning spent nuclear fuel has met the statutory conditions precedent to entering into a contract with the Secretary of Energy that provides for interim Federal storage of a limited amount of spent fuel.

Although a Commission determination is necessary before the Secretary may enter into contract negotiations, the determination does not specify the terms or authorize the execution or performance of a contract for the storage of spent fuel. Since the details of the contract are not and cannot be known at the time of a Commission determination, the environmental effects of the contract cannot be ascertained and a meaningful environmental impact statement or assessment cannot be prepared. The determination, in and of itself, has no environmental effect.

As Congress recognized, any environmental impacts that might ultimately occur result from the decision of the Secretary of Energy to enter into a specific contract with a utility, not from the prior Commission determination. Under section 136(a) of the Waste Act, this contract must provide for Federal ownership, transport, and interim storage of such amounts of spent fuel as the Commission determines cannot be stored on site. The Waste Act also specifies the nature of the environmental review that must be undertaken when the Secretary of Energy provides for Federal storage of spent fuel. Section 135(c) states that provision by the Secretary of Energy of 300 or more metric tons of storage capacity at any one Federal site shall be considered a major Federal action requiring preparation of an environmental impact statement. If the Secretary of Energy provides less than 300 metric tons of storage capacity at any one Federal site, the Secretary need only prepare an environmental assessment of the probable impacts. Thus, the Waste Act not only recognizes that environmental effects will flow from contracts entered into by the Secretary, but also provides that these effects are to be evaluated at the time the Secretary provides for interim spent fuel storage capacity at one or more Federal sites. Because, prior to that time, no environmental effects will occur, and the nature of any potential environmental effects that might occur in the future as a result of the storage contracts cannot be known with any degree of certainty, no environmental impact statement or assessment need be prepared in connection with this rulemaking action.

5. There are no other environmental documents related to this rulemaking action.

6. The environmental assessment on which this finding of no significant impact is based is contained in the Regulatory Analysis that is available for inspection as noted below.

Paperwork Reduction Act Statement

The final rule contains information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget under control number 3150-0128.

Regulatory Analysis

The Commission has prepared a regulatory analysis of the proposed regulation. The analysis identifies and examines the costs and benefits of the final rule and its alternatives. The analysis is available for inspection, and copying for a fee at the NRC Public Document Room, 1717 H Street NW., Washington, DC 20555.

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this rule, if adopted, will not have a significant economic impact on a substantial number of small entities. The addition of 10 CFR Part 53 applies solely to certain owners and operators of civilian nuclear power reactors, none of which can be considered small entities.

List of Subjects

10 CFR Part 1

Organization and functions.

10 CFR Part 53

Administrative practice and procedure, High-level waste, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements, Spent fuel, Waste treatment and disposal.

VI. Amendatory Text

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, the Nuclear Waste Policy Act of 1982, and 5 U.S.C. 553, the NRC is adopting the following new part, 10 CFR Part 53, and a related conforming amendment to 10 CFR Part 1.

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50 FR 8605
Published 3/4/85

10 CFR Parts 1 and 53

Criteria and Procedures for Determining the Adequacy of Available Spent Nuclear Fuel Storage Capacity

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule; correction.

SUMMARY: In a notice published in the Federal Register February 11, 1985 (50 FR 5548), the Nuclear Regulatory Commission established in a final rule procedures and criteria for determining whether a person owning or operating a civilian nuclear power reactor cannot reasonably provide adequate spent nuclear fuel storage capacity. The rule implemented NRC responsibilities under sections 135 (b) and (g) of the Nuclear Waste Policy Act. This document corrects minor typographical errors published in that notice of final rulemaking.

FOR FURTHER INFORMATION CONTACT: D.R. Hopkins, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Telephone: (301) 443-7878.

SUPPLEMENTARY INFORMATION: The corrections to that notice follow:

1. On page 5563, in the List of Subjects for 10 CFR Part 53, "Spent nuclear fuel" should read "Spent fuel."

2. On page 5564, in § 53.11(b)(1), "1980" should read "1990."

3. On page 5564, in § 53.12(c)(3), the word "fuel" should be added to line 8 so that it reads, "uranium (MTU) of spent nuclear fuel and."

4. On page 5565, in the § 53.13 heading, "alternatives" should be capitalized so that it reads "Alternatives."

5. On page 5566, in § 53.30(a)(8), the word "is" should be added to the last line so that it reads "additional storage capacity is needed."

Dated at Washington, DC this 28th day of February 1985.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

≫50 FR 20741
Published 5/20/85
Effective 6/19/85

10 CFR Part 1

Delegation of Subpoena Authority

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations to reflect the Commission's decision to delegate authority to the Office of Investigations to issue subpoenas where necessary or appropriate for the conduct of investigations. This amendment will permit the Office of Investigations (OI) to issue independently a subpoena during the course of investigations.

EFFECTIVE DATE: June 19, 1985.

FOR FURTHER INFORMATION CONTACT: Polly Schofield, Office of Investigations, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Telephone (301) 492-7246.

SUPPLEMENTARY INFORMATION:

Background

By memorandum dated July 20, 1982, the Commission approved SECY 82-239 (June 9, 1982) and delegated the authority to issue subpoenas to the Executive Director for Operations. Under that authority, subpoenas have been issued in five matters. In two cases subpoenas have been issued to support staff action. In three cases, including TMI where 47 subpoenas were issued, subpoenas were issued under the EDO's authority to support OI's investigations. The EDO issued subpoenas at the request of OI because OI did not have the independent authority to issue subpoenas.

In those cases where the subpoena is being used to support an OI investigation, the staff function in reviewing a subpoena is essentially (1) assuring an adequate legal basis for issuing the subpoena, (2) questioning whether the agency has exhausted other mechanisms for obtaining the information, and (3) assuring on balance that a subpoena is the appropriate mechanism to obtain the information. This review process is considered to be proper for staff subpoenas. However, this review may not be always appropriate for OI requested subpoenas in view of the separation of functions between the OI and the EDO staff organizations. It may also not be the most efficient way for OI to obtain a subpoena.

The EDO and OI agreed that OI should be delegated authority to issue subpoenas. OI would consult with the staff before issuing a subpoena to determine whether the staff already has the information being sought.

Pursuant to EDO and OI recommendations, the Commission voted on January 11, 1985, to delegate to the Director, Office of Investigations, the authority to issue subpoenas under section 161c of the Atomic Energy Act of 1954, as amended, where necessary or appropriate for the conduct of investigations.

Since these are minor, procedural amendments relating to agency organization and management, notice and opportunity for comment are not required by the Administrative Procedure Act under 5 U.S.C. 553 or by 10 CFR 2.804(d).

Environmental Impact: Categorical Exclusion

The NRC has determined that this final rule is the type of action described in categorical exclusion 10 CFR 51.22(c)(1). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this final rule.

Paperwork Reduction Act Statement

This final rule contains no information collection requirements and therefore is not subject to the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.).

List of Subjects in 10 CFR Part 1

Organization and functions.

For reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is adopting the following amendment to 10 CFR Part 1.

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50 FR 21036
Published 5/22/85
Effective 5/22/85

10 CFR Parts 1 and 51

Update of NRC Addresses and Copying Charges for Environmental Documents; Minor Correcting Amendments

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to update the addresses of the NRC's principal offices and to conform the charges for reproduction of environmental documents at the NRC's Public Document room to those found in 10 CFR Part 9. These amendments are necessary to inform the public of these administrative changes to NRC regulations.

EFFECTIVE DATE: May 22, 1985.

FOR FURTHER INFORMATION CONTACT: John Philips, Chief, Rules and Procedures Branch, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Telephone 301-492-7086.

SUPPLEMENTARY INFORMATION: On December 7, 1984, the NRC published a final rule (49 FR 47823) indicating changes in mailing addresses for several regional offices. At that time, an update of the principal offices of § 1.3, Location of principal offices and Regional Offices, was overlooked. Of the eight locations listed in § 1.3(a), two buildings have been vacated by the NRC, while three new building locations have been established.

On July 31, 1984, the NRC published a final rule (49 FR 30457) which revised the charges for copying records publicly available at the NRC Public Document Room, located at 1717 H Street, NW., Washington, D.C. At this time § 51.123 is revised to reflect current NRC copying charges.

Because these are amendments dealing with agency practice and procedures, the notice provisions of the Administrative Procedure Act do not apply pursuant to 5 U.S.C. 553(b)(A). The amendments are effective upon publication in the **Federal Register**. Good cause exists to dispense the usual 30-day delay in the effective date because the amendments are of a minor and administrative nature dealing solely with agency procedures.

Paperwork Reduction Act Statement

This final rule contains no information collection requirements and therefore is not subject to the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.).

List of Subjects

10 CFR Part 1

Organization and functions (Government agencies)

10 CFR Part 51

Administrative practice and procedure, Environmental impact statements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is adopting the following amendments to 10 CFR Parts 1 and 51.

UNITED STATES NUCLEAR REGULATORY COMMISSION
RULES and REGULATIONS
TITLE 10, CHAPTER 1, CODE OF FEDERAL REGULATIONS—ENERGY

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*Amended 43 FR 6915

PART 2 • RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS

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APPENDIX C—GENERAL POLICY AND PROCEDURE FOR NRC ENFORCEMENT ACTIONS

Authority: Secs. 161,181, 68 Stat. 948, 953, as amended (42 U.S.C. 2201, 2231); sec. 191, as amended, Pub. L. 87-615, 76 Stat. 409 (42 U.S.C. 2241); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); 5 U.S.C. 552.

Section 2.101 also issued under secs. 53, 62, 63, 81, 103, 104, 105, 68 Stat. 930, 932, 933, 935, 936, 937, 938, as amended (42 U.S.C. 2073, 2092, 2093, 2111, 2133, 2134, 2135); sec. 102, Pub. L. 91–190, 83 Stat. 853, as amended (42 U.S.C. 4332); sec. 301, 88 Stat. 1248 (42 U.S.C. 5871). Sections 2.102, 2.103, 2.104, 2.105, 2.721 also issued under secs. 102, 103, 104, 105, 183, 189, 68 Stat. 936, 937, 938, 954, 955, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2233, 2239). Section 2.105 also issued under Pub. L. 97–415, 96 Stat. 2073 (42 U.S.C. 2239). Sections 2.200–2.206 also issued under secs. 186, 234, 68 Stat. 955, 83 Stat. 444, as amended (42 U.S.C. 2236, 2282); sec. 206, 88 Stat. 1246 (42 U.S.C. 5846). Sections 2.300–2.309 also issued under Pub. L. 97–415, 96 Stat. 2071 (42 U.S.C. 2133). Sections 2.600–2.606 also issued under sec. 102, Pub. L. 91–190, 83 Stat. 853 as amended (42 U.S.C. 4332). Sections 2.700a, 2.719 also issued under 5 U.S.C. 554. Sections 2.754, 2.760, 2.770 also issued under 5 U.S.C. 557, Section 2.790 also issued under sec. 103, 68 Stat. 936, as amended (42 U.S.C. 2133) and 5 U.S.C. 552. Sections 2.800 and 2.808 also issued under 5 U.S.C. 553. Section 2.809 also issued under 5 U.S.C. 553 and sec. 29, Pub. L. 85–256, 71 Stat. 579, as amended (42 U.S.C. 2039). Appendix A also issued under sec. 6, Pub. L. 91–560, 84 Stat. 1473 (42 U.S.C. 2135). 48 FR 46489

§ 2.1 Scope.

This part governs the conduct of all proceedings, other than export and import licensing proceedings described in Part 110, under the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, for (a) granting, suspending, revoking, amending, or taking other action with respect to any license, construction permit, or application to transfer a license; (b) imposing civil penalties under section 234 of the Act; and (c) public rulemaking. 43 FR 6915

§ 2.2 Subparts.

Each subpart other than Subpart G sets forth special rules applicable to the type of proceeding described in the first section of that subpart. Subpart G sets forth general rules applicable to all types of proceedings except rule making, and should be read in conjunction with the subpart governing a particular proceeding. Subpart I sets forth special procedures to be followed in proceedings in order to safeguard and prevent disclosure of Restricted Data. 27 FR 377

§ 2.3 Resolution of conflict.

In any conflict between a general rule in Subpart G of this part and a special rule in another subpart or other part of this chapter applicable to a particular type of proceeding, the special rule governs. 28 FR 10151

§ 2.4 Definitions.

As used in this part,

(a) "ACRS" means the Advisory Committee on Reactor Safeguards established by the Act.

(b) "Act" means the Atomic Energy Act of 1954, as amended (68 Stat. 919).

(c) "Adjudication" means the process for the formulation of an order for the final disposition of the whole or any part of any proceeding subject to this part, other than rule making. 27 FR 377

(d) "Department" means the Department of Energy established by the Department of Energy Organization Act (Pub. L. 95-91, 91 Stat. 565 42 U.S.C. 7101 *et seq.*) to the extent that the Department, or its duly authorized representatives, exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to sections 104 (b), (c) and (d) of the Energy Reorganization Act of 1974 (Pub. L. 93-438, 88 Stat. 1233 at 1237, 42 U.S.C. 5814) and retransferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Pub. L. 95-91, 91 Stat. 565 at 577-578, 42 U.S.C. 7151). 45 FR 14199

(e) "Commission" means the Commission of five members or a quorum thereof sitting as a body, as provided by section 201 of the Energy Reorganization Act of 1974 (88 Stat. 1242), or any officer to whom has been delegated authority pursuant to section 161n of the Act. 27 FR 377

(f) [Reserved] 40 FR 8774

(g) "Facility" means a production facility or a utilization facility as defined in § 50.2 of this chapter. 28 FR 10151

(h) "Administrative Law Judge" means an individual appointed pursuant to section 11 of the Administrative Procedure Act to conduct proceedings subject to this part. 38 FR 2330

(i) "License" means a license or construction permit issued by the Commission.

(j) "Licensee" means a person who is authorized to conduct activities under a license or construction permit issued by the Commission. 40 FR 8774

(k) "Public Document Room" means the place at 1717 H Street NW., Washington, D.C., at which public records of the Commission will ordinarily be made available for inspection. 28 FR 10151

(l) [Reserved] 40 FR 8774

(m) "Secretary" means the Secretary to the Commission. 29 FR 12189

(n) "Contested proceeding" means (1) a proceeding in which there is a controversy between the staff of the Commission and the applicant for a license concerning the issuance of the license or any of the terms or conditions thereof or (2) a proceeding in which a petition for leave to intervene in opposition to an application for a license has been granted or is pending before the Commission. 31 FR 12774

(o) "Person" means (1) any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, government agency other than the Commission or the Department, except that the Department shall be considered a person with respect to those facilities of the Department specified in section 202 of the Energy Reorganization Act of 1974 (88 Stat. 1244),[4] any State or any political subdivision of, or any political entity within a State, any foreign government or nation or any political subdivision of any such government or nation, or other entity; and (2) any legal successor, representative, agent, or agency of the foregoing. 45 FR 14199

(p) "NRC personnel" means (1) NRC employees; (2) for the purpose of §§ 2.720 and 2.740 only, persons acting in the capacity of consultants to the Commission, regardless of the form of the contractual arrangements under which such persons act as consultants to the Commission; and (3) members of advisory boards, committees, and panels of the NRC; members of boards designated by the Commission to preside at adjudicatory proceedings; and officers or employees of Government agencies, including military personnel, assigned to duty at the NRC. 38 FR 1500

(q) "NRC records and documents" means any book, paper, map, photograph, brochure, punch card, magnetic tape, paper tape, sound recording, pamphlet, slide, motion picture, or other documentary material regardless of form or characteristics, made by, in the possession of, or under the control of the NRC pursuant to Federal law or in connection with the transaction of public business as evidence of NRC organization, functions, policies, decisions, procedures, operations, programs or other activities. "NRC records and documents" do not include objects or articles such as structures, furniture, tangible exhibits or models, or vehicles and equipment. 35 FR 19500

(r) Except as redefined in this section, words and phrases which are defined in the Act and in this chapter have the same meaning when used in this part. 40 FR 8774

(s) "Electric utility" means any entity that generates or distributes electricity and which recovers the costs of this electricity, either directly or indirectly through rates established by the entity itself or by a separate regulatory authority. Investor-owned utilities including generation or distribution subsidiaries, public utility districts, municipalities, rural electric cooperatives, and State and Federal agencies, including associations of any of the foregoing, are included within the meaning of "electric utility." 49 FR 35747

Subpart A—Procedure for Issuance, Amendment, Transfer, or Renewal of a License

27 FR 377

§ 2.100 Scope of subpart.

This subpart prescribes the procedures for issuance of a license; amendment of a license at the request of the licensee; and transfer and renewal of a license.

§ 2.101 Filing of application.

(a)(1) An application for a license or an amendment to a license shall be filed with the Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as prescribed by the applicable provisions of this chapter. A prospective applicant may confer informally with the staff prior to the filing of an application. 41 FR 15832

(2) Each application for a license for a facility or for receipt of waste radioactive material from other persons for the purpose of commercial disposal by the waste disposal licensee will be assigned a docket number. However, to allow a determination as to whether an application for a construction permit or operating license for a production or utilization facility is complete and acceptable for docketing, it will be initially treated as a tendered application after it is received and a copy of the tendered application will be available for public inspection in the Commission's Public Document Room, 1717 H Street NW., Washington, D.C. Generally, that determination will be made within a period of thirty (30) days. However, in selected construction permit applications, the Commission may decide to determine acceptability on the basis of the technical adequacy of the application as well as its completeness. In such cases, the Commission, pursuant to § 2.104(a), will direct that the notice of hearing be issued as soon as practicable after the application has been tendered, and the determination of acceptability will generally be made within a period of sixty (60) days. For docketing and other requirements for applications pursuant to Part 61 of this chapter, see paragraph (g) of this section. 47 FR 57446

(3) If the Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate, determines that a tendered application for a construction permit or operating license for a production or utilization facility, and/or any environmental report required pursuant to Subpart A of Part 51 of this chapter, or part thereof as provided in paragraphs (a)(5) or (a-1) of this section are complete and acceptable for 49 FR 9352

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[4] The Department facilities specified in section 202 are:

(1) Demonstration Liquid Metal Fast Breeder reactors when operated as part of the power generation facilities of an electric utility system, or when operated in any other manner for the purpose of demonstrating the suitability for commercial application of such a reactor.

(2) Other demonstration nuclear reactors, except those in existence on January 19, 1975, when operated as part of the power generation facilities of an electric utility system, or when operated in any other manner for the purpose of demonstrating the suitability for commercial application of such a reactor.

(3) Facilities used primarily for the receipt and storage of high-level radioactive wastes resulting from licensed activities.

(4) Retrievable Surface Storage Facilities and other facilities authorized for the express purpose of subsequent long-term storage of high-level radioactive waste generated by the Administration, which are not used for, or are part of, research and development activities.

docketing, a docket number will be assigned to the application or part thereof, and the applicant will be notified of the determination. With respect to the tendered application and/or environmental report or part thereof that is acceptable for docketing, the applicant will be requested to:

(i) Submit to the Director of Nuclear reactor Regulation of Director of Nuclear Material Safety and Safeguards, as appropriate, such additional copies as the regulations in Part 50 and Subpart A of Part 51 require;

49 FR 9352

(ii) Serve a copy on the chief executive of the municipality in which the facility is to be located or, if the facility is not to be located within a municipality, on the chief executive of the county, and serve a notice of availability of the application or environmental report on the chief executives of the municipalities or counties which have been identified in the application or environmental report as the location of all or part of the alternative sites, containing the following information: Docket number of the application, a brief description of the proposed site and facility; the location of the site and facility as primarily proposed and alternatively listed; the name, address, and telephone number of the applicant's representative who may be contacted for further information; notification that a draft environmental impact statement will be issued by the Commission and will be made available upon request to the Commission; and notification that if a request is received from the appropriate chief executive, the applicant will transmit a copy of the application and environmental report, and any changes to such documents which affect the alternative site location, to the executive who makes the request. In complying with the requirements of this paragraph (a)(3)(ii) the applicant should not make public distribution of those parts of the application subject to § 2.790(d). The applicant shall submit to the Director of Nuclear Reactor Regulation an affidavit that service of the notice of availability of the application or environmental report has been completed along with a list of names and addresses of those executives upon whom the notice was served; and

43 FR 46292

(iii) Make direct distribution of additional copies to Federal, State, and local officials in accordance with the requirements of this chapter and written instructions furnished to the applicant by the Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate. Such written instructions will be furnished as soon as practicable after all or any part of the application, or environmental report, is tendered. The copies submitted to the Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate, and distributed by the applicant shall be completely assembled documents, identified by docket number. Subsequently distributed amendments to applications, however, may include revised pages to previous submittals and, in such cases, the recipients will be responsible for inserting the revised pages.

(4) The tendered application for a construction permit or operating license for a production or utilization facility will be formally docketed upon receipt by the Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate, of the required additional copies. Distribution of the additional copies shall be deemed to be complete as of the time the copies are deposited in the mail or with a carrier prepaid for delivery to the designated addresses. The date of docketing shall be the date when the required copies are received by the Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate. Within ten (10) days after docketing the applicant shall submit to the Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate, an affidavit that distribution of the additional copies to Federal, State, and local officials has been completed in accordance with requirements of this chapter and written instructions furnished to the applicant by the Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate. Amendments to the application and environmental report shall be filed and distributed and an affidavit shall be furnished to the Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate, in the same manner as for the initial application and environmental report. If it is determined that all or any part of the tendered application and/or environmental report is incomplete and therefore not acceptable for processing, the applicant will be informed of this determination, and the respects in which the document is deficient.

41 FR 15832

(5) An applicant for a construction permit for a production or utilization facility which is subject to § 51.20(b) of this chapter, and is of the type specified in §§ 50.21(b) (2) or (3) or 50.22 of this chapter or is a testing facility may submit the information required of applicants by Part 50 of the chapter in three parts. One part shall be accompanied by the information required by § 50.30(f) of this chapter, another part shall include any information required by § 50.34(a) and, if applicable, § 50.34a of this chapter and a third part shall include any information required by § 50.33a. One part may precede or follow other parts by no longer than six (6) months except that the part including information required by § 50.33a shall be submitted in accordance with time periods specified in § 50.33a. If an applicant for a construction permit for a nuclear power reactor is exempted pursuant to § 50.33a of this chapter from filing the information described by § 50.33a of this chapter, such applicant shall file with the first part of its application an affidavit setting forth facts as to the electrical generating capacity of its system. If it is determined that any one of the parts as described above is incomplete and not acceptable for processing, the Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate, will inform the applicant of this determination and the respects in which the document is deficient. Such a determination of completeness will generally be made within a period of thirty (30) days. Except for the part including information required by § 50.33a, whichever part is filed first shall also include the fee required by §§ 50.30(e) and 170.21 of this chapter and the information required by §§50.33,50.34((a)(1), and 50.37 of this chapter. The Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate, will accept for docketing an application for a construction permit for a production or utilization facility which is subject to § 51.20(b) of this chapter, and is of the type specified in §§ 50.21(b) (2) or (3) or 50.22 of this chapter or is a testing facility where one part of the application as described above is complete and conforms to the requirements of Part 50 of this chapter. Additional parts will be docketed upon a determination by the Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate, that they are complete.

49 FR 9352

(a–1) *Early consideration of site suitability issues.* An applicant for a construction permit for a utilization facility which is subject to § 51.20(b) of this chapter and is of the type specified in §§ 50.21(b) (2) or (3) or 50.22 of this chapter or is a testing facility, may request that the Commission conduct an early review and hearing and render an early partial decision in accordance with Subpart F on issues of site suitability within the purview of the applicable provisions of Parts 50, 51 and

100 of this chapter. In such cases, the applicant for the construction permit may submit the information required of applicants by the provisions of this chapter in three or (in the case of nuclear power reactors) four parts:

49 FR 9352

(1) Part one shall include or be accompanied by any information required by §§ 50.34(a)(1) and 50.30(f) of this chapter which relates to the issue(s) of site suitability for which an early review, hearing and partial decision are sought, except that information with respect to operation of the facility at the projected initial power level need not be supplied, and shall include the information required by §§ 50.33(a) through (e) and 50.37 of this chapter. The information submitted shall also include: (i) Proposed findings on the issues of site suitability on which the applicant has requested review and a statement of the bases or the reasons for those findings, (ii) a range of postulated facility design and operation parameters that is sufficient to enable the Commission to perform the requested review of site suitability issues under the applicable provisions of Parts 50, 51 and 100, and (iii) information concerning the applicant's site selection process and long-range plans for ultimate development of the site required by § 2.603(b)(1).

(2) Part two shall include or be accompanied by the remaining information required by §§ 50.30(f), 50.33 and 50.34(a)(1) of this chapter.

(3) Part three shall include the remaining information required by §§ 50.34(a) and (in the case of a nuclear power reactor) 50.34a of this chapter.

(4) The information required for part two or part three shall be submitted during the period the partial decision on part one is effective. Submittal of the information required for part three may precede by no more than six months or follow by no more than six months the submittal of the information required for part two.

(5) Part four,[1] which is only required when the application is for a construction permit for a nuclear power reactor, shall include any information required by § 50.33a of this chapter and shall be filed in accordance with the time periods specified in § 50.33a.

42 FR 22882

(b) After the application has been docketed each applicant for a license for receipt of waste radioactive material from other persons for the purpose of commercial disposal by the waste disposal licensee except applicants under Part 61 of this chapter, who must comply with paragraph (g) of this section, shall serve a copy of the application and environmental report, as appropriate, on the chief executive of the municipality in which the activity is to be conducted or, if the activity is not to be conducted within a municipality on the chief executive of the county, and serve a notice of availability of the application or environmental report on the chief executives of the municipalities or counties which have been identified in the application or environmental report as the location of all or part of the alternative sites, containing the following information: Docket number of the application; a brief description of the proposed site and facility; the location of the site and facility as primarily proposed and alternatively listed; the name, address, and telephone number of the applicant's representative who may be contacted for further information; notification that a draft environmental impact statement will be issued by the Commission and will be made available upon request to the Commission; and notification that if a request is received from the appropriate chief executive, the applicant will transmit a copy of the application and environmental report, and any changes to such documents which affect the alternative site location, to the executive who makes the request. In complying with the requirements of this paragraph (b) the applicant should not make public distribution of those parts of the application subject to § 2.790(d). The applicant shall submit to the Director of Nuclear Material Safety and Safeguards an affidavit that service of the notice of availability of the application or environmental report has been completed along with a list of names and addresses of those executives upon whom the notice was served.

47 FR 57446

(c) The notice published in the Federal Register announcing docketing of the antitrust information portion of an application for a facility construction permit under section 103 of the Act, except for those applications described in § 2.101(e) and §2.102(d)(2), shall state that:

47 FR 9983

(1) The portion of the application filed contains the information requested by the Attorney General for the purpose of an antitrust review of the application as set forth in Appendix L to Part 50 of this chapter;

(2) Upon receipt and acceptance for docketing of the remaining portions of the application dealing with radiological health and safety and environmental matters, notice of receipt will be published in the FEDERAL REGISTER including an appropriate notice of hearing; and

41 FR 15832

(3) Any person who wishes to have his views on the antitrust matters of the application considered by the NRC and presented to the Attorney General for consideration should submit such views within sixty (60) days after publication of the notice announcing receipt and docketing of the antitrust information to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Chief, Antitrust and Economic Analysis Branch.

47 FR 9983

(d) The Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate, will give notice of the docketing of the public health and safety, common defense and security, and environmental parts of an application for a license for a facility or for receipt of waste radioactive material from other persons for the purpose of commercial disposal by the waste disposal licensee, except that for applications pursuant to Part 61 of this chapter paragraph (g) of this section applies, to the Governor or other appropriate official of the State in which the facility is to be located or the activity is to be conducted and will cause to be published in the Federal Register a notice of docketing of the application which states the purpose of the application and specifies the location at which the proposed activity would be conducted.

47 FR 57446

(e)(1) Upon receipt of the antitrust information responsive to Regulatory Guide 9.3 submitted in connection with an application for a facility operating license under section 103 of the Act, the Director of Nuclear Reactor Regulation or the Director of Nuclear Material Safety and Safeguards, as appropriate, shall publish in the Federal Register and in appropriate trade journals a "Notice of Receipt of Operating License Antitrust Information." The notice shall invite persons to submit, within thirty (30) days after publication of the notice, comments or information concerning the antitrust aspects of the application to assist the Director in determining, pursuant to section 105c of the Act, whether significant changes in the licensee's activities or proposed activities have occurred since the completion of the previous antitrust review in connection with the construction permit. The notice shall also state that persons who wish to have their views on the antitrust aspects of the application considered by the NRC and presented to the Attorney General for consideration should submit such views within thirty (30) days after publication of the notice to: U.S. Nuclear

47 FR 9983

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[1] For a construction permit application in four parts, part four shall be filed second in time since it must precede both parts two and three by a period of from 9 months to 3 years.

Regulatory Commission, Washington, D.C. 20555, Attention: Chief, Antitrust and Economic Analysis Branch.

(2) If the Director of Nuclear Reactor Regulation or the Director of Nuclear Material Safety and Safeguards, as appropriate, after reviewing any comments or information received in response to the published notice and any comments or information regarding the applicant received from the Attorney General, concludes that there have been no significant changes since the completion of the previous antitrust review in connection with the construction permit, a finding of no significant changes shall be published in the Federal Register, together with a notice stating that any request for reevaluation of such finding should be submitted within thirty (30) days of publication of the notice. If no requests for reevaluation are received within that time, the finding shall become the NRC's final determination. Requests for a reevaluation of the no significant changes determination may be accepted after the date when the Director's finding becomes final but before the issuance of the OL only if they contain new information, such as information about facts or events of antitrust significance that have occurred since that date, or information that could not reasonably have been submitted prior to that date.

(3) If, as a result of a reevaluation of the finding described in paragraph (e)(2) of this section, it is determined that there have been no significant changes, the Director of Nuclear Reactor Regulation or the Director of Nuclear Material Safety and Safeguards, as appropriate, shall deny the request and shall publish a notice of finding of no significant changes in the Federal Register. The notice and finding become the final NRC decision thirty (30) days after being made and only in the event that the Commission has not exercised sua sponte review.

(4) If the Director of Nuclear Reactor Regulation or the Director of Nuclear Material Safety and Safeguards, as appropriate, concludes that significant changes have occurred since the completion of the antitrust review in connection with the construction permit, then the provisions of § 2.102(d) apply.

47 FR 9983

(f)(1) Each application for a license to receive and possess high-level radioactive waste at a geologic repository operations area pursuant to Part 60 of this chapter and any environmental report required in connection therewith pursuant to Subpart A of Part 51 of this chapter shall be processed in accordance with the provisions of this paragraph.

49 FR 9352

(2) To allow a determination as to whether the application or environmental report is complete and acceptable for docketing, it will be initially treated as a tendered document, and a copy will be available for public inspection in the Commission's Public Document Room. Twenty copies shall be filed to enable this determination to be made.

(3) If the Director of Nuclear Material Safety and Safeguards determines that the tendered document is complete and acceptable for docketing, a docket number will be assigned and the applicant will be notified of the determination. If it is determined that all or any part of the tendered document is incomplete and therefore not acceptable for processing, the applicant will be informed of this determination and the respects in which the document is deficient.

46 FR 13971

(4) The Director may determine the environmental report to be not complete and therefore not acceptable for processing if it fails to include the required site characterization data, including the results of appropriate in situ testing at depth for each site characterized, with respect to the number of sites and media specified in section 114(f) of the Nuclear Waste Policy Act of 1982. If such a determination is made, the Director shall request the DOE to submit, within a specified time, such characterization data as the Director determines to be necessary. If the DOE fails to provide the requested data within the time specified, the application shall be subject to denial under § 2.108.

(5) With respect to any tendered document that is acceptable for docketing, the applicant will be requested to (i) submit to the Director of Nuclear Material Safety and Safeguards such additional copies as the regulations in Part 60 and Subpart A of Part 51 of this chapter require, (ii) serve a copy on the chief executive of the municipality in which the geologic repository operations area is to be located or, if the geologic repository operations area is not to be located within a municipality, on the chief executive of the county (or to the Tribal organization, if it is to be located within an Indian reservation), and (iii) make direct distribution of additional copies to Federal, State, Indian Tribe, and local officials in accordance with the requirements of this chapter and written instructions from the director of Nuclear Material Safety and Safeguards. All such copies shall be completely assembled documents, identified by docket number. Subsequently distributed amendments, however, may include revised pages to previous submittals and, in such cases, the recipients will be responsible for inserting the revised pages.

49 FR 9352

(6) The tendered document will be formally docketed upon receipt by the Director of Nuclear Material Safety and Safeguards of the required additional copies. The date of docketing shall be the date when the required copies are received by the Director of Nuclear Material Safety and Safeguards. Within ten (10) days after docketing, the applicant shall submit to the Director of Nuclear Material Safety and Safeguards a written statement that distribution of the additional copies to Federal, State, Indian Tribe, and local officials has been completed in accordance with requirements of this chapter and written instructions furnished to the applicant by the Director of Nuclear Material Safety and Safeguards. Distribution of the additional copies shall be deemed to be complete as of the time the copies are deposited in the mail or with a carrier prepaid for delivery to the designated addressees.

(7) Amendments to the application and environmental report shall be filed and distributed and a written statement shall be furnished to the Director of Nuclear Material Safety and Safeguards in the same manner as for the initial application and environmental report.

(8) The Director of Nuclear Material Safety and Safeguards will cause to be published in the Federal Register a notice of docketing which identifies the State and location at which the proposed geologic repository operations area would be located and will give notice of docketing to the governor of that State. The notice of docketing will state that the Commission finds that a hearing is required in the public interest, prior to issuance of a construction authorization, and will recite the matters specified in § 2.104(a) of this part.

46 FR 13971

(g) Each application for a license to receive radioactive waste from other persons for disposal under Part 61 of this chapter and the accompanying environmental report shall be processed in accordance with the provisions of this paragraph.

(1) To allow a determination as to whether the application or environmental report is complete and acceptable for docketing, it will be initially treated as a tendered document, and a copy will be available for public inspection in the Commission's Public Document Room 1717 H Street NW., Washington, D.C. One original and two copies shall be filed to enable this determination to be made.

(i) Upon receipt of a tendered application, the Commission will publish in the **Federal Register** notice of the filed application and will notify the governors, legislatures and other appropriate State, county, and municipal officials and tribal governing bodies of the States and areas containing or potentially affected by the activities at the proposed site and the alternative sites. The Commission will inform these officials that the Commission staff will be available for consultation pursuant to § 61.71 of this chapter. The **Federal Register** notice will note the opportunity for interested persons to submit views and comments on the tendered application for consideration by the Commission and applicant. The Commission will also notify the U.S. Bureau of Indian Affairs when tribal governing bodies are notified.

(ii) The Commission will also post a public notice in a newspaper or newspapers of general circulation in the affected States and areas summarizing information contained in the applicant's tendered application and noting the opportunity to submit views and comments.

(iii) When the Director of Nuclear Material Safety and Safeguards determines that the tendered document is complete and acceptable for docketing, a docket number will be assigned and the applicant will be notified of the determination. If it is determined that all or any part of the tendered document is incomplete and therefore not acceptable for processing, the applicant will be informed of this determination and the aspects in which the document is deficient.

47 FR 57446

(2) With respect to any tendered document that is acceptable for docketing, the applicant will be requested to (i) submit to the Director of Nuclear Material Safety and Safeguards such additional copies as the regulations in Part 61 and Subpart A of Part 51 of this chapter require, (ii) serve a copy on the chief executive of the municipality in which the waste is to be disposed of or, if the waste is not to be disposed of within a municipality, serve a copy on the chief executive of the county in which the waste is to be disposed of, (iii) make direct distribution of additional copies to Federal State, Indian Tribe, and local officials in accordance with the requirements of this chapter and written instructions from the Director of Nuclear Material Safety and Safeguards, and (iv) serve a notice of availability of the application and environmental report on the chief executives or governing bodies of the municipalities or counties which have been identified in the application and environmental report as the location of all or part of the alternative sites if copies are not distributed under paragraph (g)(2)(iii) of this section to the executives or bodies. All distributed copies shall be completely assembled documents identified by docket number. Subsequently distributed amendments, however, may include revised pages to previous submittals and, in such cases, the recipients will be responsible for inserting the revised pages. In complying with the requirements of paragraph (g) of this section the applicant shall not make public distribution of those parts of the application subject to § 2.790(d).

49 FR 9352

(3) The tendered document will be formally docketed upon receipt by the Director of Nuclear Material Safety and Safeguards of the required additional copies. Distribution of the additional copies shall be deemed to be complete as of the time the copies are deposited in the mail or with a carrier prepaid for delivery to the designated addressees. The date of docketing shall be the date when the required copies are received by the Director of Nuclear Material Safety and Safeguards. Within ten (10) days after docketing, the applicant shall submit to the Director of Nuclear Material Safety and Safeguards a written statement that distribution of the additional copies to Federal, State, Indian Tribe, and local officials has been completed in accordance with requirements of this section and written instructions furnished to the applicant by the Director of Nuclear Material Safety and Safeguards.

(4) Amendments to the application and environmental report shall be filed and distributed and a written statement shall be furnished to the Director of Nuclear Material Safety and Safeguards in the same manner as for the initial application and environmental report.

(5) The Director of Nuclear Material Safety and Safeguards will cause to be published in the **Federal Register** a notice of docketing which identifies the State and location of the proposed waste disposal facility and will give notice of docketing to the governor of that State and other officials listed in paragraph (g)(3) of this section and, in a reasonable period thereafter, publish in the **Federal Register** a notice pursuant to § 2.105 offering opportunity to request a hearing to the applicant and other affected persons.

47 FR 57446

(next page is 2-7)

§ 2.102 Administrative review of application.

(a) During review of an application by the staff, an applicant may be required to supply additional information. The staff may request any one party to the proceeding to confer with the staff informally. In the case of a docketed application for a construction permit or an operating license for a facility, the staff shall establish a schedule for its review of the application, specifying the key intermediate steps from the time of docketing until the completion of its review.

(b) The Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate, will refer the docketed application to the ACRS as required by law and in such additional cases as he or the Commission may determine to be appropriate. The ACRS will render to the Commission one or more reports as required by law or as requested by the Commission.

(c) The Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate, will make each report of the ACRS a part of the record of the docketed application, and transmit copies to the appropriate State and local officials.

37 FR 15127

(d)(1) Except as provided in paragraph (d)(2) of this section, the Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate, will refer and transmit a copy of each docketed application for a construction permit or an operating license for a utilization or production facility under section 103 of the Act to the Attorney General as required by section 105c of the Act.

(2) The requirements of paragraph (d)(1) of this section do not apply to an application for an operating license for a production or utilization facility under section 103 of the Act for which the construction permit was also issued under section 103, unless the Director of Nuclear Reactor Regulation or the Director of Nuclear Material Safety and Safeguards, as appropriate, determines, after consultation with the Attorney General and in accordance with § 2.101(e), that such review is advisable on the ground that significant changes in the licensee's activities or proposed activities have occurred subsequent to the previous review of the Attorney General and the Commission under section 105c of the Act in connection with the construction permit.

47 FR 9983

(3) The Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate, will cause the Attorney General's advice received pursuant to paragraph (d)(1) to be published in the FEDERAL REGISTER promptly upon receipt, and will make such advice a part of the record in any proceeding on antitrust matters conducted in accordance with subsection 105c(5) and section 189a of the Act. The Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate, will also cause to be published in the FEDERAL REGISTER a notice that the Attorney General has not rendered any such advice. Any notice published in the FEDERAL REGISTER pursuant to this subparagraph will also include a notice of hearing, if appropriate, or will state that any person whose interest may be affected by the proceeding may, pursuant to and in accordance with § 2.714, file a petition for leave to intervene and request a hearing on the antitrust aspects of the application. The notice will state that petitions for leave to intervene and requests for hearing shall be filed within 30 days after publication of the notice.

36 FR 13270

§ 2.103 Action on applications for byproduct, source, special nuclear material, and operator licenses.

(a) If the Director of Nuclear Reactor Regulation or the Director of Nuclear Material Safety and Safeguards, as appropriate, finds that an application for a byproduct, source, special nuclear material, or operator license complies with the requirements of the Act, the Energy Reorganization Act, and this chapter, he will issue a license. If the license is for a facility, or for receipt of waste radioactive material from other persons for the purpose of commercial disposal by the waste disposal licensee, or if it is to receive and possess high-level radioactive waste at a geologic repository operations area pursuant to Part 60 of this chapter, the Director of Nuclear Reactor Regulation or the Director of Nuclear Material Safety and Safeguards, as appropriate, will inform the State, tribal and local officials specified in § 2.104(e) of the issuance of the license. For notice of issuance requirements for licenses issued pursuant to Part 61 of this chapter, see § 2.106(d) of this part.

47 FR 57446

(b) If the Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate, finds that an application does not comply with the requirements of the Act and this chapter he may issue a notice of proposed denial or a notice of denial of the application and inform the applicant in writing of:

(1) The nature of any deficiencies or the reason for the proposed denial or the denial, and

(2) The right of the applicant to demand a hearing within twenty (20) days from the date of the notice or such longer period as may be specified in the notice.

28 FR 10151

HEARING ON APPLICATION—HOW INITIATED

§ 2.104 Notice of hearing.

(a) In the case of an application on which a hearing is required by the Act or this chapter, or in which the Commission finds that a hearing is required in the public interest, the Secretary will issue a notice of hearing to be published in the FEDERAL REGISTER as required by law at least fifteen (15) days, and in the case of an application concerning a construction permit for a facility of the type described in § 50.21(b) or § 50.22 of this chapter or a testing facility, at least thirty (30) days, prior to the date set for hearing in the notice.[1]

37 FR 15127

In addition, in the case of an application for a construction permit for a facility of the type described in § 50.22 of this chapter, or a testing facility, the notice (other than a notice pursuant to paragraph (d) of this section) shall be issued as soon as practicable after the application has been docketed: *Provided*, That if the Commission, pursuant to § 2.101(a)(2), decides to determine the acceptability of the application on the basis of its technical adequacy as well as completeness, the notice shall be issued as soon as practicable after the application has been tendered.

44 FR 47758

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[1] If the notice of hearing concerning an application for a construction permit for a facility of the type described in § 50.21(b) or § 50.22 of this chapter or a testing facility does not specify the time and place of initial hearing, a subsequent notice will be published in the FEDERAL REGISTER which will provide at least thirty (30) days notice of the time and place of that hearing. After this notice is given the presiding officer may reschedule the commencement of the initial hearing for a later date or reconvene a recessed hearing without again providing thirty (30) days notice.

43 FR 30793

37 FR 15127

The notice will state:

(1) The time, place, and nature of the hearing and/or prehearing conference, if any;

(2) The authority under which the hearing is to be held;

(3) The matters of fact and law to be considered; and

(4) The time within which answers to the notice shall be filed.

(b) In the case of an application for a construction permit for a facility on which the Act requires a hearing, the notice of hearing will, except as provided in paragraph (d) of this section and unless the Commission determines otherwise, state, in implementation of paragraph (a)(3) of this section:

(1) That, if the proceeding is a contested proceeding, the presiding officer will consider the following issues:[1]

31 FR 12774

(i) Whether in accordance with the provisions of § 50.35(a) of this chapter:

(*a*) The applicant has described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public;

(*b*) Such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration will be supplied in the final safety analysis report;

(*c*) Safety features or components, if any, which require research and development, have been described by the applicant and the applicant has identified, and there will be conducted, a research and development program reasonably designed to resolve any safety questions associated with such features or components; and

(*d*) On the basis of the foregoing, there is reasonable assurance that (*1*) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of the proposed facility; and (*2*) taking into consideration the site criteria contained in Part 100 of this chapter, the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public;

(ii) Whether the applicant is technically qualified to design and construct the proposed facility;

50 FR 18852

(iii) Whether the applicant is financially qualified to design and construct the proposed facility; except that this subject shall not be an issue if the applicant is an electric utility seeking a license to construct a production or utilization facility of the type described in § 50.21(b) or § 50.22;

31 FR 12774

(iv) Whether the issuance of a permit for the construction of the facility will be inimical to the common defense and security or to the health and safety of the public;

49 FR 9352

(v) If the application is for a construction permit for a nuclear power reactor, a testing facility, a fuel reprocessing plant, or other facility whose construction or operation has been determined by the Commission to have a significant impact on the environment, whether, in accordance with the requirements of Subpart A of Part 51 of this chapter, the construction permit should be issued as proposed.

39 FR 26279

(2) That, if the proceeding is not a contested proceeding, the presiding officer will determine (i) without conducting a de novo evaluation of the application, whether the application and the record of the proceeding contain sufficient information, and the review of the application by the Commission's staff has been adequate to support affirmative findings on (b)(1) (i) through (iii) specified in this section and a negative finding on (b)(1)(iv) specified in this section proposed to be made and the issuance of the construction permit proposed by the Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety or Safeguards, as appropriate, and (ii) if the application is for a construction permit for a nuclear power reactor, a testing facility, a fuel reprocessing plant, or other facility whose construction or operation has been determined by the Commission to have a significant impact on the environment, whether the review conducted by the Commission pursuant to the National Environmental Policy Act (NEPA) has been adequate.

49 FR 9352

(3) That, regardless of whether the proceeding is contested or uncontested, the presiding officer will, in accordance with Subpart A of Part 51 of this chapter.

(i) Determine whether the requirements of section 102(2) (A), (C) and (E) of the National Environmental Policy Act and Subpart A of Part 51 of this chapter have been complied with in the proceeding;

39 FR 26279

(ii) Independently consider the final balance among conflicting factors contained in the record of the proceeding with a view to determining the appropriate action to be taken; and

(iii) Determine whether the construction permit should be issued, denied, or appropriately conditioned to protect environmental values.

44 FR 67088

(c) In the case of an application for an operating license in which a hearing will be held, the notice of hearing will, except as provided in paragraph (d) of this section and unless the Commission determines otherwise, state, in implementation of paragraph (a)(3) of this section, that the presiding officer will consider any matters in controversy among the parties and may, where he or she determines that a serious safety, environmental, or common defense and security matter has not been raised by the parties, consider such other matter within the purview of:

37 FR 15127

(1) Whether there is reasonable assurance that construction of the facility will be substantially completed on a timely basis, in conformity with the construction permit and the application as amended, the provisions of the Act, and the regulations in this chapter;

(2) Whether the facility will operate in conformity with the application as amended, the provisions of the Act, and the regulations in this chapter;

(3) Whether there is reasonable assurance: (i) That the activities to be authorized by the operating license can be conducted without endangering the health and safety of the public, and (ii) that such activities will be conducted in compliance with the regulations in this chapter;

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[1] Issues (i) to (iv) are the issues pursuant to the Atomic Energy Act of 1954, as amended. Issue (v) is the issue pursuant to the National Environmental Policy Act of 1969.

(4) Whether the applicant is technically and financially qualified to engage in the activities to be authorized by the operating license in accordance with the regulations in this chapter, except that the issue of financial qualification shall not be considered by the presiding officer in an operating license hearing if the applicant is an electric utility seeking a license to operate a utilization facility of the type described in § 50.21(b) of § 50.22;

(5) Whether the applicable provisions of Part 140 of this chapter have been satisfied;

(6) Whether issuance of the license will be inimical to the common defense and security or to the health and safety of the public; and

(7) If the application is for an operating license for a nuclear power reactor, a testing facility, or a fuel reprocessing plant, or other facility whose operation has been determined by the Commission to have a significant impact on the environment, whether, in accordance with the requirements of Subpart A of Part 51 of this chapter, the operating license should be issued as proposed.[3]

(d) In an application for a construction permit or an operating license for a facility on which a hearing is required by the Act or this chapter, or in which the Commission finds that a hearing is required in the public interest to consider the antitrust aspects of the application, the notice of hearing will, unless the Commission determines otherwise, state:

(1) A time of the hearing, which will be as soon as practicable after the receipt of the Attorney General's advice and compliance with sections 105 and 189a of the Act and this part;[4]

(2) The presiding officer for the hearing who shall be either an administrative law judge or an atomic safety and licensing board established by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel;

(3) That the presiding officer will consider and decide whether the activities under the proposed license would create or maintain a situation inconsistent with the antitrust laws described in section 105a of the Act; and

(4) That matters of radiological health and safety and common defense and security, and matters raised under the National Environmental Policy Act of 1969, will be considered at another hearing if otherwise required or ordered to be held, for which a notice will be published pursuant to paragraphs (a) and (b) of this section, unless otherwise authorized by the Commission.

(e) The Secretary will give timely notice of the hearing to all parties and to other persons, if any, entitled by law to notice. The Secretary will transmit a notice of hearing on an application for a facility license or for a license for receipt of waste radioactive material from other persons for the purpose of commercial disposal by the waste disposal licensee and all applications for disposal under Part 61 of this chapter or for a license to receive and possess high-level radioactive waste at a geologic repository operations area pursuant to Part 60 of this chapter to the governor or other appropriate official of the State and to the chief executive of the municipality in which the facility is to be located or the activity is to be conducted or, if the facility is not to be located or the activity conducted within a municipality, to the chief executive of the county (or to the Tribal organization, if it is to be so located or conducted within an Indian reservation).

§ 2.105 Notice of proposed action.

(a) If a hearing is not required by the Act or this chapter, and if the Commission has not found that a hearing is in the public interest, it will, prior to acting thereon, cause to be published in the FEDERAL REGISTER a notice of proposed action with respect to an application for:

(1) A license for a facility;

(2) A license for receipt of waste radioactive material from other persons for the purpose of commercial disposal by the waste disposal licensee. All licenses issued under Part 61 of this chapter shall be so noticed.

(3) An amendment of a license specified in paragraph (a) (1) or (2) of this section and which involves a significant hazards consideration;

(4) An amendment to an operating license for a facility licensed under § 50.21(b) or § 50.22 or for a testing facility, as follows:

(i) If the Commission determines under § 50.58 that the amendment involves no significant hazards consideration, though it will provide notice of opportunity for a hearing pursuant to this section, it may make the amendment immediately effective and grant a hearing thereafter; or

(ii) If the Commission determines under § 50.58 and § 50.91 that an emergency or exigent situation exists and that the amendment involves no significant hazards considerations, it will provide notice of opportunity for a hearing pursuant to § 2.106 (if a hearing is requested, it will be held after issuance of the amendment);

(5) A license to receive and possess high-level radioactive waste at a geologic repository operations area pursuant to Part 60 of this chapter;

(6) An amendment to a license specified in paragraph (a)(5) of this section, or an amendment to a construction authorization granted in proceedings on an application for such a license, when such amendment would authorize actions which may significantly affect the health and safety of the public; or

(7) Any other license or amendment as to which the Commission determines that an opportunity for a public hearing should be afforded.

(8) In the case of an application for an operating license for a facility of a type described in § 50.21(b) or § 50.22 of this chapter or a testing facility, a notice of opportunity for hearing shall be issued as soon as practicable after the application has been docketed.

(9) In the case of an application for a license to receive and possess high-level radioactive waste at a geologic repository operations area, a notice of opportunity for hearing, as required by this paragraph, shall be published prior to Commission action authorizing receipt of such wastes; this requirement is in addition to the procedures set out in § 2.101(f)(8) and § 2.104 of this part, which provide for a hearing on the application prior to issuance of a construction authorization.

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[3] Issues (1) to (6) are the issues pursuant to the Atomic Energy Act of 1954, as amended. Issue (7) is the issue pursuant to the National Environmental Policy Act of 1969.

[4] As permitted by subsection 105c of the Act, with respect to proceedings in which an application for a construction permit was filed prior to December 19, 1970, and proceedings in which a written request for antitrust review of an application for an operating license to be issued under section 104b has been made by a person who intervened or sought by timely written notice to the Commission to intervene in the construction permit proceeding for the facility to obtain a determination of antitrust considerations or to advance a jurisdictional basis for such determination within 25 days after the date of publication in the FEDERAL REGISTER or notice of filing of the application for an operating license or December 19, 1970, whichever is later, the Commission may issue a construction permit or operating license which contains the conditions specified in § 50.55b of this chapter before the antitrust aspects of the application are finally resolved.

38 FR 10151

(b) The notice of proposed action will set forth:

28 FR 10151

(1) The nature of the action proposed;

36 FR 4686

(2) The manner in which a copy of the safety analysis and of the ACRS report, if any, may be obtained or examined.

27 FR 377

(c) If an application for a license is complete enough to permit all evaluations, other than completion inspection, necessary for the issuance of a construction permit and operating license, the notice of proposed issuance of a construction permit may provide that on completion of construction and inspection the operating license will be issued without further prior notice.

37 FR 15127

(d) The notice of proposed action will provide that, within thirty (30) days from the date of publication of the notice in the Federal Register, or such lesser period authorized by law as the Commission may specify:

(1) The applicant may file a request for a hearing; and

(2) Any person whose interest may be affected by the proceeding may file a petition for leave to intervene.

46 FR 55083

(e)(1) If no request for a hearing or petition for leave to intervene is filed within the time prescribed in the notice, the Director of Nuclear Reactor Regulation or the Director of Nuclear Material Safety and Safeguards, as appropriate, may take the proposed action, inform the appropriate State and local officials, and publish in the Federal Register a notice of issuance of the license or other action.

(2) If a request for a hearing or a petition for leave to intervene is filed within the time prescribed in the notice, the presiding officer who shall be an Atomic Safety and Licensing Board established by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition, and the Secretary or the presiding officer will issue a notice of hearing or an appropriate order. The presiding officer designated to rule on a request or petition concerning the antitrust aspects of an application may be either an Administrative Law Judge or an Atomic Safety and Licensing Board.

46 FR 55083

35 FR 19655

(f) Applications for facility licenses under section 103 of the Act and for facility operating licenses under section 104b of the Act as to which any person intervened or sought by timely written notice to the Commission to intervene in the construction permit proceeding to obtain a determination of antitrust considerations or to advance a jurisdictional basis for such determination are also subject to the provisions of §§ 2.101(b) and 2.102(d).

38 FR 9585

§ 2.106 Notice of issuance.

(a) The Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate, will cause to be published in the Federal Register notice of, and will inform the State and local officials specified in § 2.104(e) of the issuance of:

(1) A license or an amendment of a license for which a notice of proposed action has been previously published; and

(2) An amendment of a license for a facility of the type described in § 50.21(b) or § 50.22 of this chapter, or a testing facility, whether or not a notice of proposed action has been previously published.

37 FR 15127

(b) The notice of issuance will set forth:

(1) The nature of the license or amendment;

(2) The manner in which copies of the safety analysis, if any, may be obtained and examined; and

(3) A finding that the application for the license or amendment complies with the requirements of the Act and this chapter.

46 FR 13971

(c) The Director of Nuclear Material Safety and Safeguards will also cause to be published in the Federal Register notice of, and will inform the State, local, and Tribal officials specified in § 2.104(e) of any action with respect to, an application for a license to receive and possess high-level radioactive waste at a geologic repository operations area pursuant to Part 60 of this chapter, or for the amendment to such license for which a notice of proposed action has been previously published.

47 FR 57446

(d) The Director of Nuclear Material Safety and Safeguards will also cause to be published in the Federal Register notice of, and will inform the State and local officials or tribal governing body specified in § 2.104(e) of any licensing action with respect to a license to receive radioactive waste from other persons for disposal under Part 61 of this chapter or the amendment of such a license for which a notice of proposed action has been previously published.

28 FR 10151

§ 2.107 Withdrawal of application.

(a) The Commission may permit an applicant to withdraw an application prior to the issuance of a notice of hearing on such terms and conditions as it may prescribe, or may, on receiving a request for withdrawal of an application, deny the application or dismiss it with prejudice. Withdrawal of an application after the issuance of a notice of hearing shall be on such terms as the presiding officer may prescribe.

27 FR 377

(b) The withdrawal of an application does not authorize the removal of any document from the files of the Commission.

(c) The Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate, will cause to be published in the Federal Register a notice of the withdrawal of an application if notice of receipt of the application has been previously published.

§ 2.108 Denial of application for failure to supply information.

(a) The Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate, may deny an application if an applicant fails to respond to a request for additional information within thirty (30) days from the date of the request, or within such other time as may be specified.

27 FR 377

(b) The Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate, will cause to be published in the FEDERAL REGISTER a notice of denial when notice of receipt of the application has previously been published, but no notice of hearing has yet been published. The notice of denial will provide that, within thirty (30) days after the date of publication in the FEDERAL REGISTER (1) the applicant may demand a hearing, and (2) any person whose interest may be affected by the proceeding may file a petition for leave to intervene.

(c) When both a notice of receipt of the application and a notice of hearing have been published, the presiding officer, upon a motion made by the staff pursuant to § 2.730, will rule whether an application should be denied by the Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate, pursuant to paragraph (a).

39 FR 43195

(next page is 20-11)

§ 2.109 Effect of timely renewal application.

28 FR 10151

If, at least thirty (30) days prior to the expiration of an existing license authorizing any activity of a continuing nature, a licensee files an application for a renewal or for a new license for the activity so authorized, the existing license will not be deemed to have expired until the application has been finally determined.

§ 2.110 Filing and administrative action on submittals for design review or early review of site suitability issues.

42 FR 22882

(a)(1) A submittal pursuant to Appendix O of Part 50 of this chapter shall be subject to §§ 2.101(a) and 2.790 to the same extent as if it were an application for a permit or license.

(2) Except as specifically provided otherwise by the provisions of Appendix Q to Part 50 of this chapter, a submittal pursuant to Appendix Q shall be subject to § 2.101 (a)(2)–(a)(4) to the same extent as if it were an application for a permit or license.

(b) Upon initiation of review by the staff of a submittal of a type described in paragraph (a)(1) of this section, the Director of Nuclear Reactor Regulation shall publish in the FEDERAL REGISTER a notice of receipt of the submittal, inviting comments from interested persons within 60 days of publication or such other time as may be specified, for consideration by the staff and ACRS in their review.

(c) Upon completion of review by the staff and the ACRS of a submittal of the type described in paragraph (a)(1) of this section, the Director of Nuclear Reactor Regulation shall publish in the FEDERAL REGISTER a determination as to whether or not the design is acceptable, subject to such conditions as may be appropriate, and place in the Public Document Room an analysis of the design in the form of a report.

§ 2.111 Prohibition of sex discrimination.

40 FR 8774

No person shall on the ground of sex be excluded from participation in, be denied a license under, be denied the benefits of, or be subjected to discrimination under any program or activity carried on or receiving Federal assistance under the Act or the Energy Reorganization Act of 1974.

Subpart B—Procedure for Imposing Requirements by Order, or for Modification, Suspension, or Revocation of a License, or for Imposing Civil Penalties

§ 2.200 Scope of subpart.

48 FR 44170

(a) This subpart prescribes the procedure in cases initiated by the staff, or upon a request by any person, to impose requirements by order, or to modify, suspend, or revoke a license, or to take other action as may be proper, against any person subject to the jurisdiction of the Commission.

42 FR 28891

(b) This subpart also prescribes the procedures in cases initiated by the staff to impose civil penalties pursuant to section 234 of the Act and section 206 of the Energy Reorganization Act of 1974.

§ 2.201 Notice of violation.

48 FR 44170

(a) Before instituting any proceeding to modify, suspend, or revoke a license or to take other action for alleged violation of any provision of the Act or this chapter or the conditions of the license, the Director, Office of Inspection and Enforcement, a Regional Administrator, or the designee of either, will serve on the licensee or other person subject to the jurisdiction of the Commission a written notice of violation, except as provided in paragraph (c) of this section. The notice of violation will concisely state the alleged violation and will require that the licensee or any other person submit, within twenty (20) days of the date of the notice or other specified time, a written explanation or statement in reply including:

(1) Corrective steps which have been taken by the licensee or other person and the results achieved;

(2) Corrective steps which will be taken; and

(3) The date when full compliance will be achieved.

(b) The notice may require the licensee or other person subject to the jurisdiction of the Commission to admit or deny the violation and to state the reasons for the violation, if admitted. It may provide that, if an adequate reply is not received within the time specified in the notice, the Director, Office of Inspection and Enforcement, may issue an order to show cause why the license should not be modified, suspended or revoked or why such other action as may be proper should not be taken.

27 FR 10826

(c) When the Director, Office of Inspection and Enforcement, finds that the public health, safety, or interest so requires, or that the violation is willful, the notice of violation may be omitted and an order to show cause issued.

§ 2.202 Order to show cause.

45 FR 3250

(a) The Executive Director for Operations during an emergency as determined by the EDO, and Director of Nuclear Reactor Regulation, Director of Nuclear Material Safety and Safeguards, Director, Office of Inspection and Enforcement, and Director, Office of Administration, as appropriate may institute a proceeding to modify, suspend, or revoke a license or for such other action as may be proper by serving on the licensee an order to show cause which will:

28 FR 10151

(1) Allege the violations with which the licensee is charged, or the potentially hazardous conditions or other facts deemed to be sufficient ground for the **proposed** action.

27 FR 377

(2) Provide that the licensee may file a written answer to the order under oath or affirmation within twenty (20) days of its date, or such other time as may be specified in the order;

(3) Inform the licensee of his right, within twenty (20) days of that date of the order, or such other time as may be specified in the order, to demand a hearing;

(4) Specify the issues; and

(5) State the effective date of the order.

(b) A licensee may respond to an order to show cause by filing a written answer under oath or affirmation. The answer shall specifically admit or deny each allegation or charge made in the order to show cause, and may set forth the matters of fact and law on which the licensee relies. The answer may demand a hearing.

(c) If the answer demands a hearing, the Commission will issue an order designating the time and place of hearing.

(d) An answer or stipulation may consent to the entry of an order in substantially the form proposed in the order to show cause.

(e) The consent of the licensee to the entry of an order shall constitute a waiver by the licensee of a hearing, findings of fact and conclusions of law, and of all right to seek Commission and judicial review or to contest the validity of the order in any forum. The order shall have the same force and effect as an order made after hearing by a presiding officer or the Commission.

(f) When the Executive Director for Operations, during an emergency as determined by the EDO, or the Director of Nuclear Reactor Regulation, Director of Nuclear Material Safety and Safeguards, Director, Office of Inspection and Enforcement, as appropriate, finds that the public health, safety, or interest so requires or that the violation is willful, the order to show cause may provide, for stated reasons, that the prodposed action be temporarily effective pending further order.

45 FR 3250

§ 2.203 Settlement and compromise.

At any time after the issuance of an order designating the time and place of hearing in a proceeding to modify, suspend, or revoke a license or for other action, the staff and a licensee or other person may enter into a stipulation for the settlement of the proceeding or the compromise of a civil penalty. The stipulation or compromise shall be subject to approval by the designated presiding officer or, if none has been designated, by the Chief Administrative Law Judge, according due weight to the position of the staff. The presiding officer, or if none has been designated, the Chief Administrative Law Judge, may order such adjudication of the issues as he may deem to be required in the public interest to dispose of the proceeding. If approved, the terms of the settlement or compromise shall be embodied in a decision or order settling and discontinuing the proceeding.

§ 2.204 Order for modification of license.

The Commission may modify a license by issuing an amendment on notice to the licensee that he may demand a hearing with respect to all or any part of the amendment within twenty (20) days from the date of the notice or such longer period as the notice may provide. The amendment will become effective on the expiration of the period during which the licensee may demand a hearing, or, in the event that he demands a hearing, on the date specified in an order made following the hearing. When the Commission finds that the public health, safety, or interest so requires, the order may be made effective immediately.

28 FR 10151

§ 2.205 Civil penalties.

(a) Before instituting any proceeding to impose a civil penalty under section 234 of the Act, the Director of Nuclear Reactor Regulation, Director of Nuclear Material Safety and Safeguards, Director, Office of Inspection and Enforcement, as appropriate,shall serve a written notice of violation upon the person charged. This notice may be included in a notice issued pursuant to § 2.201. The notice of violation shall specify the date or dates, facts, and the nature of the alleged act or omission with which the person is charged, and shall identify specifically the particular provision or provisions of the law, rule, regulation, license, permit, or cease and desist order involved in the alleged violation and shall state the amount of each penalty which the Director of Nuclear Reactor Regulation, Director of Nuclear Material Safety and Safeguards, Director, Office of Inspection and Enforcement, as appropriate,proposes to impose. The notice of violation shall also advise the person charged that the civil penalty may be paid in the amount specified therein, or the proposed imposition of the civil penalty may be protested in its entirety or in part, by a written answer, either denying the violation, or showing extenuating circumstances. The notice of violation shall advise the person charged that upon failure to pay a civil penalty subsequently determined by the Commission, if any, the penalty may, unless compromised, remitted or mitigated, be collected by civil action pursuant to section 234c of the Act.

36 FR 16894

(b) Within twenty (20) days of the date of a notice of violation or other time specified in the notice, the person charged may either pay the penalty in the amount proposed or answer the notice of violation. The answer to the notice of violation shall state any facts, explanations, and arguments, denying the charges of violation, or demonstrating any extenuating circumstances, error in the notice of violation, or other reason why the penalty should not be imposed and may request remission or mitigation of the penalty.

(c) If the person charged with violation fails to answer within the time specified in paragraph (b) of this section, the Director of Nuclear Reactor Regulation, Director of Nuclear Material Safety and Safeguards, Director, Office of Inspection and Enforcement, as appropriate,will issue an order imposing the civil penalty in the amount set forth in the notice of violation described in paragraph (a) of this section.

(d) If the person charged with violation files an answer to the notice of violation, the Director of Nuclear Reactor Regulation, Director of Nuclear Material Safety and Safeguards, Director, Office of Inspection and Enforcement, as appropriate, upon consideration of the answer, will issue an order dismissing the proceeding or imposing, mitigating, or remitting the civil penalty. The person charged may, within twenty (20) days of the date of the order or other time specified in the order, request a hearing.

36 FR 16894

(e) If the person charged with violation requests a hearing, the Commission will issue an order designating the time and place of hearing.

(f) If a hearing is held, an order will be issued after the hearing by the presiding officer or the Commission dismissing the proceeding or imposing, mitigating, or remitting the civil penalty.

(g) The Director of Nuclear Reactor Regulation, Director of Nuclear Material Safety and Safeguards, Director, Office of Inspection and Enforcement, as appropriate, may compromise any civil penalty, subject to the provisions of § 2.203.

36 FR 18173

(h) If the civil penalty is not compromised, or is not remitted by the Director of Nuclear Reactor Regulation Director of Nuclear Material Safety and Safeguards, Director, Office of Inspection and Enforcement, as appropriate,the presiding officer or the Commission, and if payment is not made within ten (10) days following either the service of the order described in paragraph (c) or (f) of this section, or the expiration of the time for requesting a hearing described in paragraph (d) of this section, no such request having been made, the Director of Nuclear Reactor Regulation, Director of Nuclear Material Safety and Safeguards, Director, Office of Inspection and Enforcement, as appropriate,may refer the matter to the Attorney General for collection.

36 FR 16894

(i) Except when payment is made after compromise or mitigation by the Department of Justice or as ordered by a court of the United States, following reference of the matter to the Attorney General for collection, payment of civil penalties imposed under section 234 of the Act shall be made by check, draft, or money order payable to the Treasurer of the United States, and mailed to the Director of Nuclear Reactor Regulation, Director of Nuclear Material Safety and Safeguards, Director, Office of Inspection and Enforcement, as appropriate.

§ 2.206 Requests for action under this subpart.

(a) Any person may file a request for the Director of Nuclear Reactor Regulation, Director of Nuclear Material Safety and Safeguards, Director, Office of Inspection and Enforcement, as appropriate, to institute a proceeding pursuant to § 2.202 to modify, suspend or revoke a license, or for such other action as may be proper. Such a request shall be addressed to the Director of Nuclear Reactor Regulation, Director of Nuclear Material Safety and Safeguards, Director, Office of Inspection and Enforcement, as appropriate, and shall be filed either: (1) By delivery to the Public Document Room at 1717 H Street NW., Washington, D.C., or (2) by mail or telegram addressed to the Director of Nuclear Reactor Regulation, Director of Nuclear Material Safety and Safeguards, Director, Office of Inspection and Enforcement, as appropriate, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. The requests shall specify the action requested and set forth the facts that constitute the basis for the request.

(b) Within a reasonable time after a request pursuant to paragraph (a) of this section has been received, the Director of Nuclear Reactor Regulation, Director of Nuclear Material Safety and Safeguards, Director, Office of Inspection and Enforcement, as appropriate shall either institute the requested proceeding in accordance with this subpart or shall advise the person who made the request in writing that no proceeding will be instituted in whole or in part, with respect to his request, and the reasons therefor.

39 FR 12353

(c)(1) Director's decisions under this section will be filed with the Office of the Secretary. Within twenty-five (25) days after the date of the Director's decision under this section that no proceeding will be instituted or other action taken in whole or in part, the Commission may on its own motion review that decision, in whole or in part, to determine if the Director has abused his discretion. This review power does not limit in any way either the Commission's supervisory power over delegated staff actions or the Commission's power to consult with the staff on a formal or informal basis regarding institution of proceedings under this section.

45 FR 74693

(2) No petition or other request for Commission review of a Director's decision under this section will be entertained by the Commission.

42 FR 36239

Subpart C—Procedures Under Section 192 for the Issuance of Temporary Operating Licenses

§ 2.300 Scope of subpart.

This subpart prescribes the procedures for issuing a temporary operating license and specifies the framework for Commission determinations. These procedures apply in any proceeding where an applicant has applied for a final operating license for a utilization facility (licensable under sections 103 of 104b. of the Atomic Energy Act (Act) and otherwise requiring a licensing hearing pursuant to section 189a.) and the applicant, pursuant to section 192 of the Act and § 50.57(d) of this chapter, petitions the Commission for a temporary operating license authorizing fuel loading, testing, and initial low power operation (or for an amendment to a temporary operating license authorizing operation at an increased power level), pending action by the Commission on the application for the final operating license.

§ 2.301 Filing of petition and accompanying affidavits.

(a) Before November 14, 1983, an applicant for an operating license may file a written petition for a temporary operating license with the Commission for each such facility. At the same time that the applicant files with the Commission for its temporary operating license, it must serve the petition, including the accompanying affidavits, on all parties to the proceeding for the issuance of the final operating license. The applicant may file any such petition at any time after the documents called for by section 192 of the Act and § 50.57(d) of this chapter are issued.

48 FR 46489

(b) The initial petition for a temporary operating license for each such facility shall, in accordance with section 192 of the Act and § 50.57(d) of this chapter, be limited initially to a specified time and to a power level not to exceed 5 percent of the facility's rated full thermal power for that specified time. After the Commission issues a temporary operating license for any such facility, the licensee may file subsequent petitions with the Commission, using the procedure described in paragraph (a), which request the Commission to amend the temporary operating license to allow facility operation at incremental stages beyond the initial 5 percent level for specified times, up to and including operation at full power, pending completion of the proceeding on the final operating license.

(c) The Commission has full discretion to determine the initial power level up to 5 percent and the incremental increases in power levels it will authorize and the period for which the authorization is granted. It will not grant a temporary operating license or an amendment to that license for a period lasting beyond the date the final operating license is granted; and the temporary operating license and any amendments to that license will expire when the final operating license is issued.

§ 2.302 Contents of affidavits.

The applicant's petition for a temporary operating license or an amendment to that license shall be accompanied by an affidavit or affidavits setting forth the specific facts upon which the petitioner relies to justify issuance of the temporary operating license or the amendment to that license. Any such affidavit and any affidavit filed in response shall state separately the specific facts and arguments and include the exhibits upon which the person relies. The facts asserted in any affidavit filed shall be sworn to or affirmed by persons having knowledge of those facts, and a statement to this effect shall affirmatively appear in the affidavit. Except under unusual circumstances, such persons should be those who would be available to substantiate orally the facts asserted, as the Commission deems appropriate. Any such affidavit shall be accompanied by a list of documents relied on to support the facts stated in the affidavit and such documents shall be or have been provided to the Commission so that they can be made available for inspection.

48 FR 46489

§ 2.303 Notice of petition.

(a) The Commission will promptly publish notice of each petition for issuance of a temporary operating license and any subsequent petitions for amendments to that license in the **Federal Register** and in such trade or news publications as the Commission deems appropriate in order to give reasonable notice to persons who might have a potential interest in the grant of such a temporary operating license or an amendment to that license. The notice will inform such persons of the arrangements for their access to the petition and supporting affidavits. Any person may file responsive affidavits in support of, or in opposition to, the petition within 30 days after the publication of such notice in the **Federal Register**. The Commission thereafter will act as expeditiously as possible to reach a determination on such petitions.

(b) If, after it has filed its petiton, the applicant files additional documents which provide substantive data or argument material to the issuance of its temporary operating license, these and the petition will be renoticed to initiate a new 30-day period.

§ 2.304 Responsive affidavits.

Responsive affidavits in support of an application for a temporary operating license shall be accompanied by a short and concise statement of the material facts which support the issuance of that license. Responsive affidavits in opposition to the petition shall be accompanied by a short and concise statement of the material facts as to which it is contended that there exists a substantial issue concerning the issuance of the temporary operating license or an amendment to that license. Any responsive affidavit and any accompanying statement shall be served on all parties to the proceeding for the issuance of the final operating license. Any document referenced in support of a responsive affidavit shall be or have been provided to the Commission so that it can be made available for inspection.

§ 2.305 Commission authorization.

(a) Issuance of a temporary operating license or an amendment to that license shall be pursuant to a final order of the Commission itself which recites the reasons for such authorization as called for in section 192 of the Act and § 50.57(d) of this chapter.

48 FR 46489

(b) The requirements of section 189a. of the Act with respect to the issuance of or an amendment to a utilization facility license shall not apply to the issuance of or an amendment to a temporary operating license. Except as provided in paragraphs (b) (1) and (2) of this section, Subparts A and G of this part, shall not apply.

(1) Sections 2.701, 2.702, 2.706–2.713, 2.758, 2.772, and 2.790 of subpart G of this part shall apply to the consideration of a petition for the issuance of or an amendment to such a temporary operating license;

(2) That portion of § 2.780 of Subpart G of this part which prohibits communications with persons outside the Commission shall apply. Communications between the Commissioners, their immediate staffs and other NRC officials who advise the Commissioners in the exercise of their quasi-judicial functions, and the regulatory staff, shall be permitted. Copies of any such written communications and summaries of any such oral communications, except communications not prohibited by § 2.780, shall be placed promptly in the public document room and served on the parties to the proceedings.

§ 2.306 Hearing on final operating license.

(a) Issuance of a temporary operating license under section 192 of the Act and § 50.57(d) of this chapter shall not prejudice the right of any party in a proceeding for the issuance of the final operating license to pursue properly admitted issues in a hearing required pursuant to section 189a. of the Act. Failure to assert any ground for denial or limitation of such a temporary operating license shall not bar the assertion of such ground in connection with the issuance of a subsequent final operating license. No party shall argue the issuance or denial of a temporary operating license by the Commission as support for its position in a proceeding for the issuance of the final operating license.

(b) Any hearing on the application for the final operating license for a facility required pursuant to section 189a. of the Act shall be concluded as promptly as practicable. The Commission will suspend the temporary operating license if it finds that the applicant is not prosecuting the application for the final operating license with due diligence. The Commission may suspend the license for other public health and safety or common defense and security reasons.

§ 2.307 Notification to the Commission

48 FR 46489

(a) Any party to a hearing required pursuant to section 189a. of the Act on the final operating license for a facility for which a temporary operating license has been issued under section 192 of the Act and § 50.57(d) of this chapter, and any member of the Atomic Safety and Licensing Board (ASLB) conducting such a hearing, shall promptly notify the Commission of any information that:

(1) The terms and conditions of the temporary operating license are not being met; or that

(2) Such terms and conditions are not sufficient to provide reasonable assurance that operation of the facility will provide adequate protection to the public health and safety and to the environment during the period of the facility's temporary operation.

(b) The notification shall be accompanied by a statement of material facts supporting the assertion, and it shall be served on all the parties to the proceedings.

(c) The holder of a temporary operating license may respond to the notification. Any response shall be served on all the parties to the proceedings.

§ 2.308 Use of informal procedures.

The Commission ordinarily will not use formal adjudicatory procedures in issuing a temporary operating license and will develop informal procedures case-by-case to resolve particular issues as they arise.

48 FR 46489

§ 2.309 Enforcement.

The Commission may modify, suspend or revoke a temporary operating license, or impose a civil penalty pursuant to sections 186 and 234 of the Act and Subpart B of this part.

Subpart D—Additional Procedures Applicable to Proceedings for the Issuance of Licenses To Construct or Operate Nuclear Power Plants of Duplicate Design at Multiple Sites

§ 2.400 Scope of subpart.

This subpart describes procedures applicable to licensing proceedings which involve the consideration in hearings of a number of applications, filed by one or more applicants pursuant to Appendix N of Part 50 of this chapter, for licenses to construct and operate nuclear power reactors of essentially the same design to be located at different sites.

§ 2.401 Notice of hearing on applications pursuant to Appendix N of Part 50 for construction permits.

40 FR 2976

(a) In the case of applications pursuant to Appendix N of Part 50 of this chapter for construction permits for nuclear power reactors of the type described in § 50.22 of this chapter, the Secretary will issue notices of hearing pursuant to § 2.104.

(b) The notice of hearing will also state the time and place of the hearings on any separate phase of the proceeding.

§ 2.402 Separate hearings on separate issues; consolidation of proceedings.

(a) In the case of applications pursuant to Appendix N of Part 50 of this chapter for construction permits for nuclear power reactors of a type described in § 50.22 of this chapter, the Commission or the presiding officer may order separate hearings on particular phases of the proceeding, such as matters related to the acceptability of the design of the reactor, in the context of the site parameters postulated for the design; environmental matters; or antitrust aspects of the application.

43 FR 17798

(b) If a separate hearing is held on a particular phase of the proceeding, the Commission or presiding officers of each affected proceeding may, pursuant to § 2.716, consolidate for hearing on that phase two or more proceedings to consider common issues relating to the applications involved in the proceedings, if it finds that such action will be conducive to the proper dispatch of its business and to the ends of justice. In fixing the place of any such consolidated hearing due regard will be given to the convenience and necessity of the parties, petitioners for leave to intervene or the attorneys or representatives of such persons, and the public interest.

§ 2.403 Notice of proposed action on applications for operating licenses pursuant to Appendix N of Part 50.

In the case of applications pursuant to Appendix N of Part 50 of this chapter for operating licenses for nuclear power reactors, if the Commission has not found that a hearing is in the public interest, the Director of Nuclear Reactor Regulation will, prior to acting thereon, cause to be published in the FEDERAL REGISTER, pursuant to § 2.105, a notice of proposed action with respect to each application as soon as practicable after the applications have been docketed.

§ 2.404 Hearings on applications for operating licenses pursuant to Appendix N of Part 50.

If a request for a hearing and/or petition for leave to intervene is filed within the time prescribed in the notice of proposed action on an application for an operating license pursuant to Appendix N of Part 50 of this chapter with respect to a specific reactor(s) at a specific site and the Commission or an atomic safety and licensing board designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel has issued a notice of hearing or other appropriate order, the Commission or the atomic safety and licensing board may order separate hearings on particular phases of the proceeding and/or consolidate for hearing two or more proceedings in the manner described in § 2.402.

40 FR 2976

§ 2.405 Initial decisions in consolidated hearings.

At the conclusion of any hearing held pursuant to this subpart, the presiding officer will render a partial initial decision which may be appealed pursuant to § 2.762. No construction permit or full power operating license will be issued until an initial decision has been issued on all phases of the hearing and all issues under the Act and the National Environmental Policy Act of 1969 appropriate to the proceeding have been resolved.

§ 2.406 Finality of decisions on separate issues.

Notwithstanding any other provision of this chapter, in a proceeding conducted pursuant to this subpart and Appendix N of Part 50 of this chapter, no matter which has been reserved for consideration in one phase of the hearing shall be considered at another phase of the hearing except on the basis of significant new information that substantially affects the conclusion(s) reached at the other phase or other good cause.

§ 2.407 Applicability of other sections.

The provisions of Subparts A and G relating to construction permits and operating licenses apply, respectively, to construction permits and operating licenses subject to this subpart, except as qualified by the provisions of this subpart.

Subpart E—Additional Procedures Applicable to Proceedings for the Issuance of Licenses To Manufacture Nuclear Power Reactors To Be Operated at Sites Not Identified in the License Application and Related Licensing Proceedings

§ 2.500 Scope of subpart.

This subpart prescribes procedures applicable to licensing proceedings which involve the consideration in separate hearings of an application for a license to manufacture nuclear power reactors pursuant to Appendix M of Part 50 of this chapter, and applications for construction permits and operating licenses for nuclear power reactors which have been the subject of such an application for a license to manufacture such facilities (manufacturing license).

§ 2.501 Notice of hearing on application pursuant to Appendix M of Part 50 for a license to manufacture nuclear power reactors.

(a) In the case of an application pursuant to Appendix M of Part 50 of this chapter for a license to manufacture nuclear power reactors of the type described in § 50.22 of this chapter to be operated at sites not identified in the license application, the Secretary will issue a notice of hearing to be published in the FEDERAL REGISTER at least thirty (30) days prior to the date set for hearing in the notice.[1] The notice shall be issued as soon as practicable after the application has been docketed. The notice will state:

(1) The time, place, and nature of the hearing and/or the prehearing conference;

(2) The authority within which the hearing is to be held;

(3) The matters of fact and law to be considered; and

(4) The time within which answers to the notice shall be filed.

(b) The issues stated in the notice of hearing pursuant to paragraph (a) of this section will not involve consideration of the particular sites at which any of the nuclear power reactors to be manufactured will be located and operated. Except as the Commission determines otherwise, the notice of hearing will state:

(1) That, if the proceeding is a contested proceeding, the presiding officer will consider the following issues:[2]

(i) Whether the applicant has described the proposed design of, and the site parameters postulated for, the reactor(s), including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public;

(ii) Whether such further technical or design information as may be required to complete the design report and which can reasonably be left for later consideration, will be supplied in a supplement to the design report;

(iii) Whether safety features or components, if any, which require research and development have been described by the applicant and the applicant has identified, and there will be conducted a research and development program reasonably designed to resolve any safety questions associated with such features or components;

(iv) Whether on the basis of the foregoing, there is reasonable assurance that (A) such safety questions will be satisfactorily resolved before any of the proposed nuclear power reactors are removed from the manufacturing site, and (B) taking into consideration the site criteria contained in Part 100 of this chapter, the proposed reactor(s) can be constructed and operated at sites having characteristics that fall within the site parameters postulated for the design of the reactor(s) without undue risk to the health and safety of the public;

(v) Whether the applicant is technically and financially qualified to design and manufacture the proposed reactor(s).

(vi) Whether the issuance of a license for manufacture of the reactor(s) will be inimical to the common defense and security or to the health and safety of the public; and

(vii) Whether, in accordance with the requirements of Subpart A of Part 51 and Appendix M of Part 50 of this chapter, the license should be issued as proposed.

(2) That, if the proceeding is not a contested proceeding, the presiding officer will determine (i) without conducting a de novo evaluation of the application, whether the application and the record of the proceeding contain sufficient information, and the review of the application by the Commission's staff has been adequate to support affirmative findings on paragraphs (b)(1) (i) through (v) of this section and a negative finding on paragraph (b)(1)(vi) of this section proposed to be made and the issuance of the license to manufacture proposed by the Director of Nuclear Reactor Regulation, and (ii) whether the review conducted by the Commission pursuant to the National Environmental Policy Act (NEPA) has been adequate.

(3) That, regardless of whether the proceeding is contested or uncontested, the presiding officer will, in accordance with Subpart A of Part 51 and paragraph 3 of Appendix M of Part 50 of this chapter,

(i) Determine whether the requirements of section 102(2) (A), (C) and (E) of the National Environmental Policy Act and Subpart A of Part 51 of this chapter have been complied with in the proceeding;

(ii) Independently consider the final balance among conflicting factors contained in the record of the proceeding with a view to determining the appropriate action to be taken; and

(iii) Determine whether the manufacturing license should be issued, denied or appropriately conditioned to protect environmental values.

(c) The place of hearing on an application for a manufacturing license will be Washington, D.C., or such other location as the Commission deems appropriate.

§ 2.502 Notice of hearing on application for a permit to construct a nuclear power reactor manufactured pursuant to a Commission license issued pursuant to Appendix M of Part 50 of this chapter at the site at which the reactor is to be operated.

The issues stated for consideration in the notice of hearing on an application for a permit to construct a nuclear power reactor(s) which is the subject of an application for a manufacturing license pursuant to Appendix M of Part 50 of this chapter, will be those stated in § 2.104(b) and, in addition, whether the site on which the facility is to be operated falls within the postulated site parameters specified in the relevant application for a manufacturing license.

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[1] The thirty (30) day requirement of this paragraph is not applicable to a notice of the time and place of hearing published by the presiding officer after the notice of hearing described in this section has been published.

[2] Issues (i) and (vi) are the issues pursuant to the Atomic Energy Act of 1954, as amended. Issue (vii) is the issue pursuant to the National Environmental Policy Act of 1969.

§ 2.503 Finality of decisions on separate issues.

Notwithstanding any other provision of this chapter, no matter which has been resolved at an earlier stage of the licensing process which involves a manufacturing license, a permit to construct a reactor for which a manufacturing license is sought, a license to operate such a reactor, and any amendment to such permit or licenses shall be determined to be at issue in any subsequent state of the licensing process except on the basis of significant new information that substantially affects the conclusion(s) reached at the earlier stage or other good cause.

§ 2.504 Applicability of other sections.

38 FR 30251

The provisions of Subparts A and G relating to construction permits apply to manufacturing licenses subject to this subpart, with respect to matters of radiological health and safety, environmental protection, and the common defense and security, except that § 2.104 (a) and (b) do not apply to manufacturing licenses. The provisions of Subparts A and G relating to construction permits and operating licenses apply, respectively, to construction permits and operating licenses subject to this subpart, except as qualified by the provisions of this subpart.

42FR22882

Subpart F—Additional Procedures Applicable to Early Partial Decisions on Site Suitability Issues in Connection With an Application for a Permit To Construct Certain Utilization Facilities

§ 2.600 Scope of subpart.

49 FR 9352

This subpart prescribes procedures applicable to licensing proceedings which involve an early submittal of site suitability information in accordance with § 2.101(a–1), and a hearing and early partial decision on issues of site suitability, in connection with an application for a permit to construct a utilization facility which is subject to § 51.20(b) of this chapter and is of the type specified in §§ 50.21(b) (2) or (3) or 50.22 of this chapter or is a testing facility.

§ 2.601 Applicability of other sections.

42 FR 22882

The provisions of Subparts A and G relating to applications for construction permits and proceedings thereon apply, respectively, to applications and proceedings in accordance with this subpart, except as specifically provided otherwise by the provisions of this subpart.

§ 2.602 Filing fees.

Each application which contains a request for early review of site suitability issues under the procedures of this subpart shall be accompanied by any fee required by § 50.30(e) and Part 170 of this chapter.

§ 2.603 Acceptance and docketing of application for early review of site suitability issues.

42 FR 22882

(a) Each part of an application submitted in accordance with § 2.101(a–1) of this part will be initially treated as a tendered application. If it is determined that any one of the parts as described in § 2.101(a–1) is incomplete and not acceptable for processing, the Director of Nuclear Reactor Regulation will inform the applicant of this determination and the respects in which the document is deficient. Such a determination of completeness will generally be made within a period of thirty (30) days.

49 FR 9352

(b)(1) The Director of Nuclear Reactor Regulation will accept for docketing an application for a construction permit for a utilization facility which is subject to § 51.20(b) of this chapter and is of the type specified in §§ 50.21(b) (2) or (3) or 50.22 or is a testing facility where part one of the application as described in § 2.101(a–1) is complete. Part one of an application will not be considered complete unless it contains proposed findings as required by § 2.101(a–1)(1)(i) and unless it describes the applicant's site selection process, specifies the extent to which that process involves the consideration of alternative sites, explains the relationship between that process and the application for early review of site suitability issues, and briefly describes the applicant's long-range plans for ultimate development of the site. Upon assignment of a docket number, the procedures in § 2.101 (a)(3) and (a)(4) relating to formal docketing and the submission and distribution of additional copies of the application shall be followed.

42 FR 22882

(b) (2) Additional parts of the application will be docketed upon a determination by the Director of Nuclear Reactor Regulation that they are complete.

(c) If part one of the application is docketed, the Director of Nuclear Reactor Regulation will cause to be published in the Federal Register and send to the Governor or other appropriate official of the State in which the site is located, a notice of docketing of the application which states the purpose of the application, states the location of the proposed site, states that a notice of hearing will be published, requests comments within 120 days or such other time as may be specified on the initiation or outcome of an early site review from Federal, State, and local agencies and interested persons, and in the case of applications filed under section 103 of the Act, states that a person who wishes to have his views on the antitrust aspects of the application presented to the Attorney General for consideration shall submit such views in accordance with a subsequent notice that will be published in the Federal Register. In the case of a nuclear power reactor, such subsequent notice will be published following submission of the information required by § 50.33a.

§ 2.604 Notice of hearing on application for early review of site suitability issues.

(a) Where an applicant for a construction permit for a utilization facility subject to this subpart requests an early review and hearing and an early partial decision on issues of site suitability pursuant to § 2.101(a–1), the provisions in the notice of hearing setting forth the matters of fact and law to be considered, as required by § 2.104, shall be modified so as to relate only to the site suitability issue or issues under review.

(b) After docketing of part two of the application, as provided in §§ 2.101(a–1) and 2.603, a supplementary notice of hearing will be published pursuant to § 2.104 with respect to the remaining unresolved issues in the proceeding within the scope of § 2.104. Such supplementary notice of hearing will provide that any person whose interest may be affected by the proceeding and who desires to participate as a party in the resolution of the remaining issues shall file a petition for leave to intervene pursuant to § 2.714 within the time prescribed in the notice. Such supplementary notice will also provide appropriate opportunities for participation by a representative of an interested state under § 2.715(c) and for limited appearances pursuant to § 2.715 (a).

42 FR 22882

(c) Any person who was permitted to intervene as a party pursuant to the initial notice of hearing on site suitability issues and who was not dismissed or did not withdraw as a party may continue to participate as a party to the proceeding with respect to the remaining unresolved issues, provided that within the time prescribed for filing of petitions for leave to intervene in the supplementary notice of hearing, he files a notice of his intent to continue as a party, along with a supporting affidavit identifying the specific aspect or aspects of the subject matter of the proceeding as to which he wishes to continue to participate as a party, and setting forth with particularity the basis for his contentions with regard to each such aspect or aspects. A party who files a nontimely notice of intent to continue as a party may be dismissed from the proceeding, absent a determination that the party has made a substantial showing of good cause for failure to file on time, and with particular reference to the factors specified in §§ 2.714(a)(1)–(4) and 2.714(d). The notice will be ruled upon by the Commission or atomic safety and licensing board designated to rule on petitions for leave to intervene.

(d) To the maximum extent practicable, the membership of the atomic safety and licensing board designated to preside in the proceeding on the remaining unresolved issues pursuant to the supplemental notice of hearing will be the same as the membership designated to preside in the initial notice of hearing on site suitability issues.

§ 2.605 Additional considerations.

(a) The Commission will not conduct more than one review of site suitability issues with regard to a particular site prior to filing and review of part two of the application described in § 2.101 (a–1) of this part.

(b) The Commission, upon its own initiative, or upon the motion of any party to the proceeding filed at least sixty (60) days prior to the date of the commencement of the evidentiary hearing on site suitability issues, may decline to initiate an early hearing or render an early partial decision on any issue or issues of site suitability:

49 FR 9352

(1) In cases where no partial decision on the relative merits of the proposed site and alternative sites under Subpart A of Part 51 is requested, upon determination that there is a reasonable liklihood that further review would identify one or more preferable alternative sites and the partial decision on one or more site suitability issues would lead to an irreversible and irretrievable commitment of resources prior to the submittal of the remainder of the information required by § 50.30(f) of this chapter that would prejudice the later review and decision on such alternative sites; or

42 FR 22882

(2) In cases where it appears that an early partial decision on any issue or issues of site suitability would not be in the public interest considering (i) the degree of likelihood that any early findings on those issues would retain their validity in later reviews, (ii) the objections, if any, of cognizant state or local government agencies to the conduct of an early review on those issues, and (iii) the possible effect on the public interest and the parties of having an early, if not necessarily conclusive, resolution of those issues.

49 FR 9352

§ 2.606 Partial decisions on site suitability issues.

(a) The provisions of §§ 2.754, 2.755, 2.760, 2.761, 2.762, 2.763, and 2.764(a) shall apply to any partial initial decision rendered in accordance with this subpart. Section 2.764(b) shall not apply to any partial initial decision rendered in accordance with this subpart. No limited work authorization may be issued pursuant to § 50.10(e) of Part 50 of this chapter and no construction permit may be issued without completion of the full review required by section 102(2) of the National Environmental Policy Act of 1969, as amended, and Subpart A of Part 51 of this chapter. The authority of the Commission and/or Appeal Board to review such a partial initial decision *sua sponte*, or to raise *sua sponte* an issue that has not been raised by the parties, will be exercised within the same time period as in the case of a full decision relating to the issuance of a construction permit.

(b)(1) A partial decision on one or more site suitability issues pursuant to the applicable provisions of Part 50, Subpart A of Part 51, and Part 100 of this chapter issued in accordance with this subpart shall (i) clearly identify the site to which the partial decision applies and (ii) indicate to what extent additional information may be needed and additional review may be required to enable the Commission to determine in accordance with the provisions of the Act and the applicable provisions of the regulations in this chapter whether a construction permit for a facility to be located on the site identified in the partial decision should be issued or denied.

42 FR 22882

(2) Following completion of Commission or Atomic Safety and Licensing Appeal Board review, as appropriate, of the partial initial decision of the Atomic Safety and Licensing Board, after hearing, on the site suitability issues, the partial decision shall remain in effect either for a period of five years or, where the applicant for the construction permit has made timely submittal of the information required to support the application as provided in § 2.101(a-1), until the proceeding for a permit to construct a facility on the site identified in the partial decision has been concluded,[3] unless the Commission, Atomic Safety and Licensing Appeal Board, or Atomic Safety and Licensing Board, upon its own initiative or upon motion by a party to the proceeding, finds that there exists significant new information that substantially affects the earlier conclusions and reopens the hearing record on site suitability issues. Upon good cause shown, the Commission may extend the five year period during which a partial decision shall remain in effect for a reasonable period of time not to exceed one year.

Subpart G—Rules of General Applicability

39 FR 17972

§ 2.700 Scope of subpart.

The general rules in this subpart govern procedure in all adjudications initiated by the issuance of an order to show cause, an order pursuant to § 2.205(e), a notice of hearing, a notice of proposed action issued pursuant to § 2.105, or a notice issued pursuant to § 2.102(d)(3).

47 FR 4490

§ 2.700a Exceptions.

(a) Consistent with 5 U.S.C. 554(a)(4) of the Administrative Procedure Act, the Commission may provide alternative procedures in adjudications to the extent that there is involved the conduct of military or foreign affairs functions.

(b) This rule shall apply to proceedings in progress where hearings have already been requested or ordered as well as to future proceedings.

33 FR 6707

§ 2.701 Filing of documents.

(a) Documents shall be filed with the Commission in adjudications subject to this part either: (1) By delivery to the Public Document Room at 1717 H Street NW., Washington, D.C., or (2) by mail or telegram addressed to the Secretary, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Chief, Docketing and Service Section.

29 FR 12829

(b) All documents offered for filing shall be accompanied by proof of service upon all parties to the proceeding or their attorneys of record as required by law or by rule or order of the Commission. The staff of the Commission shall be deemed to be a party.

27 FR 377

(c) Filing by mail or telegram will be deemed to be complete as of the time of deposit in the mail or with a telegraph company.

37 FR 28710

§ 2.702 Docket.

The Secretary will maintain a docket for each proceeding subject to this part, commencing with the issuance of the initial notice of hearing, notice of consideration of issuance of facility operating license or other proposed action specified in § 2.105, or order to show cause.

29 FR 12829

The Secretary will maintain all files and records, including the transcripts of testimony and exhibits and all papers, correspondence, decisions and orders filed or issued.

27 FR 377

§ 2.703 Notice of hearing.

(a) In a proceeding in which the terms of a notice of hearing are not otherwise prescribed by this part, the order or notice of hearing will state:

(1) The nature of the hearing, and its time and place, or a statement that the time and place will be fixed by subsequent order;

(2) The legal authority and jurisdiction under which the hearing is to be held;

(3) The matters of fact and law asserted or to be considered; and

(4) The time within which an answer shall be filed.

(b) The time and place of hearing will be fixed with due regard for the convenience of the parties or their representatives, the nature of the proceeding, and the public interest.

31 FR 16309

§ 2.704 Designation of presiding officer, disqualification, unavailability.

(a) The Commission may provide in the notice of hearing that one or more members of the Commission, or an atomic safety and licensing board, or a named officer who has been delegated final authority in the matter, shall preside.

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[3] The partial decision on site suitability issues shall be incorporated in the decision regarding issuance of a construction permit to the extent that it serves as a basis for the decision on a specific site issue(s).

35 FR 11459 If the Commission does not so provide, the Chairman of the Atomic Safety and Licensing Board Panel will issue an order designating an atomic safety and licensing board appointed pursuant to section 191 of the Atomic Energy Act of 1954, as amended, or, if the Commission has not provided for the hearing to be conducted by an atomic safety and licensing board, the Chief Administrative Law Judge will issue an order designating an administrative law judge appointed pursuant to section 3105 of title 5 of the United States Code.

40 FR 51995 (b) If a designated presiding officer or a designated member of an atomic safety and licensing board deems himself disqualified to preside or to participate as a board member in the hearing, he shall withdraw by notice on the record and shall notify the Commission or the Chairman of the Atomic Safety and Licensing Board Panel, as appropriate, of his withdrawal.

(c) If a party deems the presiding officer or a designated member of an atomic safety and licensing board to be disqualified, he may move that the presiding officer or the board member disqualify himself. The motion shall be supported by affidavits setting forth the alleged grounds for disqualification. If the presiding officer does not grant the motion or the board member does not disqualify himself, the motion shall be referred to the Commission or the Atomic Safety and Licensing Appeal Board, as appropriate, which will determine the sufficiency of the grounds alleged.

(d) If a presiding officer or a designated member of an atomic safety and licensing board becomes unavailable during the course of a hearing, the Commission or the Chairman of the Atomic Safety and Licensing Board Panel, as appropriate, will designate another presiding officer or atomic safety and licensing board member. If he becomes unavailable after the hearing has been concluded:

(1)(i) The Commission may designate another presiding officer to make the decision; or

(ii) The Chairman of the Atomic Safety and Licensing Board Panel or the Commission, as appropriate, may designate another atomic safety and licensing board member to participate in the decision;

(2) The Commission may direct that the record be certified to it for decision, except in adjudications in which exceptions to the initial decision may be taken to the Atomic Safety and Licensing Appeal Board; or

(3) The Commission may designate another presiding officer.

(e) In the event of substitution of a presiding officer or a designated member of an atomic safety and licensing board for the one originally designated, any motion predicated upon the substitution shall be made within five (5) days thereafter.

27 FR 377 § 2.705 Answer.

(a) Within twenty (20) days after service of the notice of hearing, or such other time as may be specified in the notice of hearing, a party may file an answer which shall concisely state: (1) The nature of his defense or other position; (2) the items of the specification of issues he controverts and those he does not controvert; and (3) whether he proposes to appear and present evidence.

(b) If facts are alleged in the specification of issues, the answer shall admit or deny specifically each material allegation of fact; or, where the party has no knowledge or information sufficient to form a belief, the answer may so state and the statement shall have the effect of a denial. Material allegations of fact not denied shall be deemed to be admitted. Matters alleged as affirmative defenses or positions shall be separately stated and identified and, in the absence of a reply, shall be deemed to be controverted.

(c) If a party does not oppose an order or proposed action embodied in or accompanying the notice of hearing, or does not wish to appear and present evidence at the hearing, the answer shall so state. In lieu of appearing at the hearing, a party may request leave to file a statement under oath or affirmation of reasons why the proposed order or action should not be issued or should differ from that proposed. Such a statement, if accepted, will be accorded whatever weight is deemed proper.

43 FR 17798 § 2.706 Reply.

A party may file a reply to an answer within ten (10) days after it is served.

37 FR 15127 § 2.707 Default.

On failure of a party to file an answer or pleading within the time prescribed in this part or as specified in the notice of hearing or pleading; to appear at a hearing or prehearing conference, to comply with any prehearing order entered pursuant to § 2.751a or § 2.752, or to comply with any discovery order entered by the presiding officer pursuant to § 2.740, the Commission or the presiding officer[4] may make such orders in regard to the failure as are just, including, among others, the following:

(a) Without further notice, find the facts as to the matters regarding which the order was made in accordance with the claim of the party obtaining the order, and enter such order as may be appropriate; or

(b) Proceed without further notice to take proof on the issues specified.

27 FR 377 § 2.708 Formal requirements for documents.

(a) Each document filed in an adjudication subject to this part to which a docket number has been assigned shall bear the docket number and title of the proceeding.

(b) Each document shall be bound on the left side and typewritten, printed or otherwise reproduced in permanent form on good unglazed paper of standard letterhead size. Each page shall begin not less than one and one-quarter inches from the top, with side and bottom margins of not less than one and one-quarter inches. Text shall be double-spaced, except that quotations may be single-spaced and indented. The requirements of this paragraph do not apply to original documents or admissible copies offered as exhibits, or to specially prepared exhibits.

28 FR 10151 (c) The original of each document shall be signed in ink by the party or his authorized representative, or by an attorney having authority with respect to it. The capacity of the person signing, his address, and the date shall be stated. The signature of a person signing in a representative capacity is a representation that the document has been subscribed in the capacity specified with full authority, that he has read it and knows the contents, that to the best of his knowledge, information, and belief the statements made in it are true, and that it is not interposed for delay. If a document is not signed, or is signed with intent to defeat the purpose of this section, it may be stricken.

45 FR 49535 (d) Except as otherwise provided by this part or by order, a pleading (or other document) other than correspondence shall be filed in an original and two conformed copies.

27 FR 377 (e) The first document filed by any person in a proceeding shall designate the name and address of a person on whom service may be made.

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[4] When a reference is made to the Commission or the presiding officer in this subpart and a presiding officer has been designated, the specified action will be taken by the presiding officer, unless otherwise provided.

PART 2 ● RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS

(f) A document filed by telegraph need not comply with the formal requirements of paragraphs (b), (c), and (d) of this section if an original and copies otherwise complying with all of the requirements of this section are mailed within two (2) days thereafter to the Secretary, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Chief, Docketing and Service Section. 39 FR 35332

§ 2.709 Acceptance for filing.

A document which fails to conform to the requirements of § 2.708 may be refused acceptance for filing and may be returned with an indication of the reason for nonacceptance. Any matter so tendered but not accepted for filing shall not be entered on the Commission's docket. 27 FR 377

§ 2.710 Computation of time.

In computing any period of time, the day of the act, event, or default after which the designated period of time begins to run is not included. The last day of the period so computed is included unless it is a Saturday, Sunday, or legal holiday at the place where the action or event is to occur, in which event the period runs until the end of the next day which is neither a Saturday, Sunday, nor holiday. Whenever a party has the right or is required to do some act within a prescribed period after the service of a notice or other paper upon him or her and the notice or paper is served upon by mail, five (5) days shall be added to the prescribed period. Only two (2) days shall be added when a document is served by express mail. 46 FR 58279

§ 2.711 Extension and reduction of time limits.

(a) Except as otherwise provided by law, whenever an act is required or allowed to be done at or within a specified time, the time fixed or the period of time prescribed may for good cause be extended or shortened by the Commission or the presiding officer, or by stipulation approved by the Commission or the presiding officer.

(b) In any instance in which this part does not prescribe a time limit for an action to be taken in the proceeding, the Commission or the presiding officer may set a time limit for that action. 37 FR 15127

§ 2.712 Service of papers, methods, proof.

(a) *Service of papers by the Commission.* Except for subpoenas, the Commission will serve all orders, decisions, notices, and other papers issued by it upon all parties. 28 FR 10151

(b) *Who may be served.* Any paper required to be served upon a party shall be served upon him or upon the representative designated by him or by law to receive service of papers. When a party has appeared by attorney, service must be made upon the attorney of record. 31 FR 4389

(c) *How Service may be made.* Service may be made by personal delivery, by first class, certified or registered mail including air mail, by telegraph, or as otherwise authorized by law. Where there are numerous parties to a proceeding, the Commission may make special provision regarding the service of papers. The presiding officer may require service by express mail upon some or all parties and the presiding officer. 46 FR 58279

(d) *When service complete.* Service upon a party is complete:

(1) By personal delivery, on handing the paper to the individual, or leaving it at his office with his clerk or other person in charge or, if there is no one in charge, leaving it in a conspicuous place therein or, if the office is closed or the person to be served has no office, leaving it at his usual place of residence with some person of suitable age and discretion then residing there;

(2) By telegraph, when deposited with a telegraph company, properly addressed and with charges prepaid;

(3) By mail, on deposit in the United States mail, properly stamped and addressed; or

(4) When service cannot be effected in a manner provided by paragraphs (d) (1) to (3) inclusive of this section in any other manner authorized by law.

(e) *Proof of service.* Proof of service, stating the name and address of the person on whom served and the manner and date of service, shall be shown for each document filed, and may be made by:

(1) Written acknowledgment of the party served or his counsel;

(2) The certificate of counsel if he has made the service; or

(3) The affidavit of the person making the service. 27 FR 377

(f) *Free copying and service.* Except in an antitrust proceeding, in any adjudicatory proceeding on an application for a license or an amendment thereto, the Commission, upon request by a party other than the applicant, will copy and serve without cost to that party that party's testimony (including attachments), proposed findings of fact and conclusions of law, and responses to discovery requests. These documents should be filed with Docketing and Service not less than five days before they are due to be submitted to an adjudicatory board, unless the presiding officer provides otherwise.[1] * 45 FR 49535

§ 2.713 Appearance and practice before the Commission in adjudicatory proceedings.

(a) Standards of Practice. In the exercise of their functions under this subpart, the Commission, the Atomic Safety and Licensing Appeal Boards, the Atomic Safety and Licensing Boards, and Administrative Law Judges function in a quasijudicial capacity. Accordingly, parties and their representatives in proceedings subject to this subpart are expected to conduct themselves with honor, dignity, and decorum as they should before a court of law.

(b) Representation. A person may appear in an adjudication on his or her own behalf or by an attorney-at-law. A partnership, corporation or unincorporated association may be represented by a duly authorized member or officer, or by an attorney-at-law. A party may be represented by an attorney-at-law provided the attorney is in good standing and has been admitted to practice before any Court of the United States, the District of Columbia, or the highest court of any State, territory, or possession of the United States. Any person appearing in a representative capacity shall file with the Commission a written notice of appearance which shall state his or her name, address, and telephone number; the name and address of the person on whose behalf he or she appears; and, in the case of an attorney-at-law, the basis of his or her eligibility as a representative or, in the case of another representative, the basis of his or her authority to act on behalf of the party. 45 FR 69877

(c) Reprimand, Censure or Suspension from the Proceeding.

(1) A presiding officer, an Atomic Safety and Licensing Appeal Board, or the Commission may, if necessary for the orderly conduct of a proceeding, reprimand, censure or suspend from participation in the particular proceeding pending before it any party or representative of a party who shall refuse to comply with its directions, or who shall be guilty of disorderly, disruptive, or contemptuous conduct.

(2) A reprimand, a censure or a suspension which is ordered to run for one day or less shall be ordered with grounds stated on the record of the proceeding and shall advise the person disciplined of the right to appeal pursuant to paragraph (c)(3) of this section. A suspension which is ordered for a longer period shall be in writing, shall state the grounds on which it is based, and shall advise the person suspended of the right to appeal and to

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*[1] This paragraph is suspended until further action of the Commission. 46 FR 13681

request a stay pursuant to paragraphs (c)(3) and (c)(4) of this section. A proceeding may be stayed for a reasonable time in order for an affected party to obtain other representation if this would be necessary to prevent injustice.

(3) Anyone disciplined pursuant to this section may within ten (10) days after issuance of the order file an appeal with the Atomic Safety and Licensing Appeal Board or the Commission, as appropriate. The appeal shall be in writing and state concisely, with supporting argument, why the appellant believes the order was erroneous, either as a matter of fact or law. The Appeal Board or Commission, as appropriate, shall consider each appeal on the merits, including appeals in cases in which the suspension period has already run. If necessary for a full and fair consideration of the facts, the Appeal Board or Commission, as appropriate, may conduct further evidentiary hearings, or may refer the matter to another presiding officer for development of a record. In the latter event, unless the Appeal Board or the Commission, as appropriate, provides specific directions to the presiding officer, that officer shall determine the procedure to be followed and who shall present evidence, subject to applicable provisions of law. Such hearing shall commence as soon as possible. In the case of an attorney, if no appeal is taken of a suspension, or, if the suspension is upheld at the conclusion of the appeal, the presiding officer, the Appeal Board or the Commission, as appropriate, shall notify the state bar(s) to which the attorney is admitted. Such notification shall include copies of the order of suspension, and, if an appeal was taken, briefs of the parties, and the decision of the Appeal Board or Commission.

(4) A suspension exceeding 1 day shall not be effective for 72 hours from the date the suspension order is issued. Within this time a suspended individual may request a stay of the sanction from the appropriate reviewing tribunal pending appeal. No responses to the stay request from other parties will be entertained. If a timely stay request is filed, the suspension shall be stayed until the reviewing tribunal rules on the motion. The stay request shall be in writing and contain the information specified in §§ 2.788(b)(1), (2) and (4) of this part. The Appeal Board or Commission, as appropriate, shall rule on the stay request within 10 days after the filing of the motion. The Appeal Board or Commission shall consider the factors specified in §§ 2.788(e)(1) and (e)(2) of this part is determining whether to grant or deny a stay application.

45 FR 69877

43 FR 17798

§ 2.714 Intervention.

(a)(1) Any person whose interest may be affected by a proceeding and who desires to participate as a party shall file a written petition for leave to intervene. In a proceeding noticed pursuant to § 2.105, any person whose interest may be affected may also request a hearing. The petition and/or request shall be filed not later than the time specified in the notice of hearing, or as provided by the Commission, the presiding officer or the atomic safety and licensing board designated to rule on the petition and/or request, or as provided in § 2.102(d)(3). Nontimely filings will not be entertained absent a determination by the Commission, the presiding officer or the atomic safety and licensing board designated to rule on the petition and/or request, that the petition and/or request should be granted based upon a balancing of the following factors in addition to those set out in paragraph (d) of this section:

(i) Good cause, if any, for failure to file on time.

(ii) The availability of other means whereby the petitioner's interest will be protected.

(iii) The extent to which the petitioner's participation may reasonably be expected to assist in developing a sound record.

(iv) The extent to which the petitioner's interest will be represented by existing parties.

(v) The extent to which the petitioner's participation will broaden the issues or delay the proceeding.

(2) The petition shall set forth with particularity the interest of the petitioner in the proceeding, how that interest may be affected by the results of the proceeding, including the reasons why petitioner should be permitted to intervene, with particular reference to the factors in paragraph (d) of this section, and the specific aspect or aspects of the subject matter of the proceeding as to which petitioner wishes to intervene.

(3) Any person who has filed a petition for leave to intervene or who has been admitted as a party pursuant to this section may amend his petition for leave to intervene. A petition may be amended without prior approval of the presiding officer at any time up to fifteen (15) days prior to the holding of the special prehearing conference pursuant to § 2.751a, or where no special prehearing conference is held, fifteen (15) days prior to the holding of the first prehearing conference. After this time a petition may be amended only with approval of the presiding officer, based on a balancing of the factors specified in paragraph (a)(1) of this section. Such an amended petition for leave to intervene must satisfy the requirements of this paragraph (a) of this section pertaining to specificity.

(b) Not later than fifteen (15) days prior to the holding of the special prehearing conference pursuant to § 2.751a, or where no special prehearing conference is held, fifteen (15) days prior to the holding of the first prehearing conference, the petitioner shall file a supplement to his petition to intervene which must include a list of the contentions which petitioner seeks to have litigated in the matter, and the bases for each contention set forth with reasonable specificity. A petitioner who fails to file such a supplement which satisfies the requirements of this paragraph with respect to at least one contention will not be permitted to participate as a party. Additional time for filing the supplement may be granted based upon a balancing of the factors in paragraph (a)(1) of this section.

43 FR 17798

44 FR 4459

(c) Any party to a proceeding may file an answer to a petition for leave to intervene within ten (10) days after service of the petition, with particular reference to the factors set forth in paragraph (d) of this section. However, the staff may file such an answer within fifteen (15) days after service of the petition.

37 FR 28710

(d) The Commission, the presiding officer or the atomic safety and licensing board designated to rule on petitions to intervene and/or requests for hearing shall, in ruling on a petition for leave to intervene, consider the following factors, among other things:

37 FR 15127

(1) The nature of the petitioner's right under the Act to be made a party to the proceeding.

(2) The nature and extent of the petitioner's property, financial, or other interest in the proceeding.

(3) The possible effect of any order which may be entered in the proceeding on the petitioner's interest.

37 FR 28710

(e) An order permitting intervention and/or directing a hearing may be conditioned on such terms as the Commission, presiding officer or the designated atomic safety and licensing board may direct in the interests of: (1) Restricting irrelevant, duplicative, or repetitive evidence and argument, (2) having common interests represented by a spokesman, and (3) retaining authority to determine priorities and control the compass of the hearing.

37 FR 15127

(f) In any case in which, after consideration of the factors set forth in paragraph (d) of this section, the Commission or the presiding officer finds that the petitioner's interest is limited to one or more of the issues involved in the proceeding, any order allowing intervention

37 FR 15127

shall limit his participation accordingly.

(g) A person permitted to intervene becomes a party to the proceeding, subject to any limitations imposed pursuant to paragraph (f) of this section.

(h) Unless otherwise expressly provided in the order allowing intervention, the granting of a petition for leave to intervene does not change or enlarge the issues specified in the notice of hearing.

37 FR 28710

§ 2.714a Appeals from certain rulings on petitions for leave to intervene and/or requests for hearing.

43 FR 17798

(a) Notwithstanding the provisions of § 2.730(f), an order of the presiding officer or the atomic safety and licensing board designated to rule on petitions for leave to intervene and/or requests for hearing may be appealed, in accordance with the provisions of this section, to the Atomic Safety and Licensing Appeal Board within ten (10) days after service of the order. The appeal shall be asserted by the filing of a notice of appeal and accompanying supporting brief. Any other party may file a brief in support of or in opposition to the appeal within ten (10) days after service of the appeal. No other appeals from rulings on petitions and/or requests for hearing shall be allowed.

37 FR 28710

(b) An order wholly denying a petition for leave to intervene and/or request for a hearing is appealable by the petitioner on the question whether the petition and/or hearing request should have been granted in whole or in part.

(c) An order granting a petition for leave to intervene and/or request for a hearing is appealable by a party other than the petitioner on the question whether the petition and/or the request for a hearing should have been wholly denied.

43 FR 17798

§ 2.715 Participation by a person not a party.

(a) A person who is not a party may, in the discretion of the presiding officer, be permitted to make a limited appearance by making oral or written statement of his position on the issues at any session of the hearing or any prehearing conference within such limits and on such conditions as may be fixed by the presiding officer, but he may not otherwise participate in the proceeding.

28 FR 10151

(b) The Secretary will give notice of a hearing to any person who requests it prior to the issuance of the notice of hearing, and will furnish a copy of the notice of hearing to any person who requests it thereafter. When a communication bears more than one signature, the Commission will give the notice to the person first signing unless the communication clearly indicates otherwise.

43 FR 17798

(c) The presiding officer will afford representatives of an interested State, county, municipality, and/or agencies thereof, a reasonable opportunity to participate and to introduce evidence, interrogate witnesses, and advise the Commission without requiring the representative to take a position with respect to the issue. Such participants may also file proposed findings and exceptions pursuant to §§ 2.754 and 2.762 and petitions for review by the Commission pursuant to § 2.786. The presiding officer may require such representative to indicate with reasonable specificity, in advance of the hearing, the subject matters on which he desires to participate.

(d) If a matter is taken up by the Appeal Board on appeal or sua sponte or by the Commission pursuant to § 2.786 or sua sponte, a person who is not a party may, in the discretion of the Appeal Board or the Commission, respectively, be permitted to file a brief "amicus curiae". A person who is not a party and desires to file a brief must submit a motion for leave to do so which identifies the interest of the person and states the reasons why a brief is desirable. Except as otherwise provided by the Commission or the Appeal Board, such brief must be filed within the time allowed to the party whose position the brief will support. A motion of a person who is not a party to participate in oral argument before an Appeal Board or the Commission will be granted at the discretion of the Appeal Board or the Commission.

37 FR 15127

§ 2.715a Consolidation of parties in construction permit or operating license proceedings.

On motion or on its or his own initiative, the Commission or the presiding officer may order any parties in a proceeding for the issuance of a construction permit or an operating license for a production or utilization facility who have substantially the same interest that may be affected by the proceeding and who raise substantially the same questions, to consolidate their presentation of evidence, cross-examination, briefs, proposed findings of fact, and conclusions of law and argument. However, it may not order any consolidation that would prejudice the rights of any party. A consolidation under this section may be for all purposes of the proceeding, all of the issues of the proceeding, or with respect to any one or more issues thereof.

43 FR 17798

§ 2.716 Consolidation of proceedings.

On motion and for good cause shown or on its own initiative, the Commission or the presiding officers of each affected proceeding may consolidate for hearing or for other purposes two or more proceedings, or may hold joint hearings with interested States and/or other federal agencies on matters of concurrent jurisdiction, if it is found that such action will be conducive to the proper dispatch of its business and to the ends of justice and will be conducted in accordance with the other provisions of this subpart.

§ 2.717 Commencement and termination of jurisdiction of presiding officer.

38 FR 2330

(a) Unless otherwise ordered by the Commission, the jurisdiction of the presiding officer designated to conduct a hearing over the proceeding, including motions and procedural matters, commences when the proceeding commences. If no presiding officer has been designated, the Chief Administrative Law Judge has such jurisdiction or, if he is unavailable, another hearing examiner has such jurisdiction.

37 FR 28710

A proceeding is deemed to commence when a notice of hearing or a notice of proposed action pursuant to § 2.105 is issued.

31 FR 12774

When a notice of hearing provides that the presiding officer is to be a hearing examiner, the Chief Administrative Law Judge† will designate by order the hearing examiner who is to preside. The presiding officer's jurisdiction in each proceeding will terminate upon the expiration of the period within which the Commission may direct that the record be certified to it for final decision, or when the Commission renders a final decision, or when the presiding officer shall have withdrawn himself from the case upon considering himself disqualified, whichever is earliest.

28 FR 10151

(b) The Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate may issue an order and take any otherwise proper administrative action with respect to a licensee who is a party to a pending proceeding. Any order related to the subject matter of the pending proceeding may be modified by the presiding officer as appropriate for the purpose of the proceeding.

§ 2.718 Power of presiding officer.

A presiding officer has the duty to conduct a fair and impartial hearing according to law, to take appropriate action to avoid delay, and to maintain order. He has all powers necessary to those ends, including the powers to:

(a) Administer oaths and affirmations.

(b) Issue subpoenas authorized by law.

(c) Rule on offers of proof, and receive evidence.

(d) Order depositions to be taken.

(e) Regulate the course of the hearing and the conduct of the participants.

(f) Dispose of procedural requests or similar matters.

(g) Examine witnesses.

(h) Hold conferences before or during the hearing for settlement, simplification of the issues, or any other proper purpose.

(i) Certify questions to the Commission for its determination, either in his discretion or on direction of the Commission.

(j) Reopen a proceeding for the reception of further evidence at any time prior to initial decision.

27 FR 377

(k) Appoint special assistants from the Atomic Safety and Licensing Board Panel pursuant to § 2.722;

(l) Issue initial decisions; and

(m) Take any other action consistent with the Act, this chapter, and sections 551–558 of title 5 of the United States Code.

45 FR 62027

§ 2.719 Separation of functions.

(a) A presiding officer shall perform no duties inconsistent with his responsibilities as a presiding officer, and will not be responsible to or subject to the supervisor or direction of any officer or employee engaged in the performance of investigative or prosecuting functions.

35 FR 11459

(b) In any adjudication, the presiding officer may not consult any person other than a member of his staff or a special assistant as provided for in § 2.722 on any fact in issue unless on notice and opportunity for all parties to participate, except (1) as required for the disposition of *ex parte* matters as authorized by law and (2) as provided in paragraph (c) of this section.

45 FR 62027

(c) In any adjudication for the determination of any application for initial licensing, other than a contested proceeding, the presiding officer may consult (1) the staff and (2) members of the panel appointed by the Commission from which members of atomic safety and licensing boards are drawn: *Provided, however,* That in adjudications in which an appeal from the initial decision may be taken to the Atomic Safety and Licensing Appeal Board, the presiding officer shall not consult any member of the Atomic Safety and Licensing Appeal Panel on any fact in issue.

(d) Except as provided in paragraph (c) of this section and § 2.780(e), in any case of adjudication, no officer or employee of the Commission who has engaged in the performance of any investigative or prosecuting function in the case or a factually related case may participate or advise in the initial or final decision, except as a witness or counsel in the proceeding. Where an initial or final decision is stated to rest in whole or in part on fact or opinion obtained as a result of a consultation or communication authorized by paragraph (c) of this section or § 2.780(e), the substance of the communication shall be specified in the record in the proceeding and every party must be afforded an opportunity to controvert the fact or opinion. If the parties have not had an opportunity to controvert such fact or opinion prior to the filing of the decision, a party may controvert the fact or opinion by filing an appeal from the initial decision, or a petition for reconsideration of a final decision, clearly and concisely setting forth the information or agrument relied on to show the contrary.

48 FR 52282

§ 2.720 Subpoenas.

(a) On application by any party, the designated presiding officer or, if he is not available, the Chairman of the Atomic Safety and Licensing Board Panel, the Chief Administrative Law Judge† or other designated officer will issue subpoenas requiring the attendance and testimony of witnesses or the production of evidence. The officer to whom application is made may require a showing of general relevance of the testimony or evidence sought, and may withhold the subpoena if such a showing is not made, but he shall not attempt to determine the admissibility of evidence.

31 FR 160309

(b) Every subpoena will bear the name of the Commission, the name and office of the issuing officer and the title of the hearing, and will command the person to whom it is directed to attend and give testimony or produce specified documents or other things at a designated time and place. The subpoena will also advise of the quashing procedure provided in paragraph (f) of this section.

(c) Unless the service of a subpoena is acknowledged on its face by the witness or is served by an officer or employee of the Commission, it shall be served by a person who is not a party to the hearing and is not less than eighteen (18) years of age. Service of a subpoena shall be made by delivery of a copy of the subpoena to the person named in it and tendering him the fees for one day's attendance and the mileage allowed by law. When the subpoena is issued on behalf of the Commission, fees and mileage need not be tendered, and the subpoena may be served by registered mail.

(d) Witnesses summoned by subpoena shall be paid, by the party at whose instance they appear, the fees and mileage paid to witnesses in the district courts of the United States.

(e) The person serving the subpoena shall make proof of service by filing the subpoena and affidavit or acknowledgement of service with the officer before whom the witness is required to testify or produce evidence or with the Secretary. Failure to make proof of service shall not affect the validity of the service.

(f) On motion made promptly, and in any event at or before the time specified in the subpoena for compliance by the person to whom the subpoena is directed, and on notice to the party at whose instance the subpoena was issued the presiding officer or, if he is unavailable, the Commission may (1) quash or modify the subpoena if it is unreasonable or requires evidence not relevant to any matter in issue, or (2) condition denial of the motion on just and reasonable terms.

(g) On application and for good cause shown, the Commission will seek judicial enforcement of a subpoena issued to a party and which has not been quashed.

27 FR 377

(h)(1) The provisions of paragraphs (a) through (g) of this section are not applicable to the attendance and testimony of the Commissioners or NRC personnel, or to the production of records or documents in the custody thereof.

35 FR 19500

(2)(i) In a proceeding in which the NRC is a party, the NRC staff will make available one or more witnesses designated by the Executive Director for Operations for oral examination at the hearing or on deposition regarding any matter, not privileged, which is relevant to the issues in the proceeding. The attendance and testimony of the Commis-

40 FR 2973

sioners and named NRC personnel at a hearing or on deposition may not be required by the presiding officer, by subpoena or otherwise: *Provided*, That the presiding officer may, upon a showing of exceptional circumstances, such as a case in which a particular named NRC employee has direct personal knowledge of a material fact not known to the witnesses made available by the Executive Director for Operations require the attendance and testimony of named NRC personnel.

40 FR 2973

(ii) In addition, a party may file with the presiding officer written interrogatories to be answered by NRC personnel with knowledge of the facts designated by the Executive Director for Operations. Upon a finding by the presiding officer that answers to the interrogatories are necessary to a proper decision in the proceeding and that answers to the interrogatories are not reasonably obtainable from any other source, the presiding officer may require that the staff answer the interrogatories.

(iii) No deposition of a particular named NRC employee or answer to interrogatories by NRC personnel pursuant to paragraphs (h) (2) (i) and (ii) of this section shall be required before the matters in controversy in the proceeding have been identified by order of the Commission or the presiding officer, pursuant to § 2.751a, or after the beginning of the prehearing conference held pursuant to § 2.752 except upon leave of the presiding officer for good cause shown.

37 FR 15127

(iv) The provisions of § 2.740(c) and (e) shall apply to interrogatories served pursuant to this subparagraph.

(3) Records or documents in the custody of the Commissioners and NRC personnel are available for inspection and copying or photographing pursuant to §§ 2.744 and 2.790.

37 FR 28710

§ 2.721 Atomic safety and licensing boards.

(a) The Commission or the Chairman of the Atomic Safety and Licensing Board Panel may from time to time establish one or more atomic safety and licensing boards, each comprised of three members, one of whom will be qualified in the conduct of administrative proceedings and two of whom shall have such technical or other qualifications as the Commission or the Chairman of the Atomic Safety and Licensing Board Panel deems appropriate to the issues to be decided, to preside in such proceedings for granting, suspending revoking, or amending licenses or authorizations as the Commission may designate, and to perform such other adjudicatory functions as the Commission deems appropriate. The members of an atomic safety and licensing board shall be designated from the Atomic Safety and Licensing Board Panel established by the Commission.

40 FR 51995

(b) The Commission or the Chairman of the Atomic Safety and Licensing Board Panel may designate an alternate qualified in the conduct of administrative proceedings, or an alternate having technical or other qualifications, or both, for an atomic safety and licensing board established pursuant to paragraph (a) of this section. If a member of a board becomes unavailable, the Commission or the Chairman of the Atomic Safety and Licensing Board Panel may constitute the alternate qualified in the conduct of administrative proceedings, or the alternate having technical or other qualifications, as appropriate, as a member of the board by notifying the alternate who will, as of the date of such notification, serve as member of the board. In the event that an alternate is unavailable or no alternates have been designated, and a member of a board becomes unavailable, the Commission or the Chairman of the Atomic Safety and Licensing Board Panel may appoint a member of the Atomic Safety and Licensing Board Panel who is qualified in the conduct of administrative proceedings or a member having technical or other qualifications, as appropriate, as a member of the atomic safety and licensing board by notifying the appointee who will, as of the date of such notification, serve as a member of the board.

48 FR 52282

(c) In a proceeding in which an appeal from the initial decision may be taken to the Atomic Safety and Licensing Appeal Board, the Commission will not designate any members of the Appeal Panel as members or alternates of the Atomic Safety and Licensing Board established to preside in such proceeding.

46 FR 17216

(d) An atomic safety and licensing board shall have the duties and may exercise the powers of a presiding officer as granted by § 2.718 and otherwise in this part. At any time when such a board is in existence but is not actually in session, any powers which could be exercised by a presiding officer or by the Chief Administrative Law Judge* may be exercised with respect to such a proceeding by the chairman of the board having jurisdiction over it.

37 FR 15127

Two members of an atomic safety and licensing board constitute a quorum, if one of those members is the member qualified in the conduct of administrative proceedings.

§ 2.722 Special assistants to the presiding officer.

(a) In consultation with the Panel Chairman, the presiding officer may, at his discretion, appoint from the Atomic Safety and Licensing Board Panel established by the Commission, personnel to assist the presiding officer in taking evidence and preparing a suitable record for review. Such appointment may occur at any appropriate time during the proceeding but shall, at the time of the appointment, be subject to the notice and disqualification provisions as described in § 2.704. Such special assistants may function as:

(1) Technical interrogators in their individual fields of expertise. Such interrogators shall be required to study the written testimony and sit with the presiding officer to hear the presentation and cross-examination by the parties of all witnesses on the issues of the interrogators' expertise, taking a leading role in examining such witnesses to ensure that the record is as complete as possible;

45 FR 62027

(2) Upon consent of all the parties, Special Masters to hear evidentiary presentations by the parties on specific technical matters, and, upon completion of the presentation of evidence, to prepare a report that would become part of the record. Special Masters may rule on evidentiary issues brought before them, in accordance with §§ 2.743 and 2.757. Appeals from such rulings may be taken to the presiding officer in accordance with procedures which shall be established in the presiding officer's order appointing the Special Master. Special Masters' reports are advisory only; the presiding officer shall retain final authority with respect to the issues heard by the Special Master; or

(3) Alternate Atomic Safety and Licensing Board members to sit with the presiding officer, to participate in the evidentiary sessions on the issue for which the alternate members were designated by examining witnesses, and to advise the presiding officer of their conclusions through an on-the-record report. This report is advisory only; the presiding officer shall retain final authority on the issue for which the alternate member was designated.

(b) The presiding officer may, as a matter of discretion, informally seek the assistance of Members of the Atomic Safety and Licensing Board Panel to brief the presiding officer on the general technical background of subjects involving complex issues which the presiding officer might otherwise have difficulty in quickly grasping. Such informal briefings shall take place prior to the hearing on the subject involved and shall supplement the reading and study undertaken by the presiding officer. They are not subject to the procedures described in § 2.704.

MOTIONS

§ 2.730 Motions.

(a) *Presentation and disposition.* All motions shall be addressed to the Commission or, when a proceeding is pending before a presiding officer, to the presiding officer. All written motions shall be filed with the Secretary, and served on all parties to the proceeding.

39 FR 24219

(b) *Form and content.* Unless made orally on the record during a hearing, or the presiding officer directs otherwise, a motion shall be in writing, shall state with particularity the grounds and the relief sought, and shall be accompanied by any affidavits or other evidence relied on, and, as appropriate, a proposed form of order.

27 FR 377

(c) *Answers to motions.* Within ten (10) days after service of a written motion, or such other period as the Secretary or the Assistant Secretary or presiding officer may prescribe, a party may file an answer in support of or in opposition to the motion, accompanied by affidavits or other evidence. However, the staff may file such an answer within fifteen (15) days after service of a written motion. The moving party shall have no right to reply, except as permitted by the presiding officer or the Secretary or the Assistant Secretary.

43 FR 17798

(d) *Oral arguments; briefs.* No oral argument will be heard on a motion unless the presiding officer or the Commission directs otherwise. A written brief may be filed with a motion or an answer to a motion, stating the arguments and authorities relied on.

27 FR 377

(e) The Board may dispose of written motions either by written order or by ruling orally during the course of a prehearing conference or hearing. The Board should ensure that parties not present for the oral ruling are notified promptly of the order.

46 FR 30328

(f) *Interlocutory appeals to the Commission.* No interlocutory appeal may be taken to the Commission from a ruling of the presiding officer. When in the judgment of the presiding officer prompt decision is necessary to prevent detriment to the public interest or unusual delay or expense, the presiding officer may refer the ruling promptly to the Commission, and notify the parties either by announcement on the record or by written notice if the hearing is not in session.

27 FR 377

(g) *Effect of filing a motion or certification of question to the Commission.* Unless otherwise ordered, neither the filing of a motion nor the certification of a question to the Commission shall stay the proceeding or extend the time for the performance of any act.

28 FR 10151

(h) Where the motion in question is a motion to compel discovery under § 2.720(h)(2) or § 2.740(f), parties may file answers to the motion pursuant to paragraph (c) of this section. The presiding officer in his or her discretion, may order that the answer be given orally during a telephone conference or other prehearing conference, rather than in writing. If responses are given over the telephone the presiding officer shall issue a written order on the motion which summarizes the views presented by the parties. This does not preclude the presiding officer from issuing a prior oral ruling on the matter which is effective at the time of such ruling, provided that the terms of the ruling are incorporated in the subsequent written order.

46 FR 58279

§ 2.731 Order of procedure.

The presiding officer or the Commission will designate the order of procedure at a hearing. The proponent of an order will ordinarily open and close.

27 FR 377

§ 2.732 Burden of proof.

Unless otherwise ordered by the presiding officer, the applicant or the proponent of an order has the burden of proof.

27 FR 377

§ 2.733 Examination by experts.

A party may request the presiding officer to permit a qualified individual who has scientific or technical training or experience to participate on behalf of that party in the examination and crossexamination of expert witnesses. The presiding officer may permit such individual to participate on behalf of the party in the examination and cross-examination of expert witnesses, where it would serve the purpose of furthering the conduct of the proceeding, upon finding (a) that the individual is qualified by scientific or technical training or experience to contribute to the development of an adequate decisional record in the proceeding by the conduct of such examination or cross-examination, (b) that the individual has read any written testimony on which he intends to examine or cross-examine and any documents to be used or referred to in the course of the examination or cross-examination, and (c) that the individual has prepared himself to conduct a meaningful and expeditious examination or cross-examination. Examination or cross-examination conducted pursuant to this section shall be limited to areas within the expertise of the individual conducting the examination or cross-examination. The party on behalf of whom such examination or cross-examination is conducted and his attorney shall be responsible for the conduct of examination or cross-examination by such individuals.

37 FR 15127

DEPOSITIONS AND WRITTEN INTERROGATORIES. DISCOVERY. ADMISSION. EVIDENCE

§ 2.740 General provisions governing discovery.

(a) *Discovery methods.* Parties may obtain discovery by one or more of the following methods: Depositions upon oral examination or written interrogatories (§ 2.740a); written interrogatories (§ 2.740b); production of documents or things or permission to enter upon land or other property, for inspection and other purposes (§ 2.741); and requests for admission (§ 2.742).

(b) *Scope of discovery.* Unless otherwise limited by order of the presiding officer in accordance with this section, the scope of discovery is as follows:

(1) *In general.* Parties may obtain discovery regarding any matter, not privileged, which is relevant to the subject matter involved in the proceeding, whether it relates to the claim or defense

37 FR 15127

of the party seeking discovery or to the claim or defense of any other party, including the existence, description, nature, custody, condition, and location of any books, documents, or other tangible things and the identity and location of persons having knowledge of any discoverable matter. In a proceeding on an application for a construction permit or an operating license for a production or utilization facility, discovery shall begin only after the prehearing conference provided for in § 2.751a and shall relate only to those matters in controversy which have been identified by the Commission or the presiding officer in the prehearing order entered at the conclusion of that prehearing conference. In such a proceeding, no discovery shall be had after the beginning of the prehearing conference held pursuant to § 2.752 except upon leave of the presiding officer upon good cause shown. It is not ground for objection that the information sought will be inadmissible at the hearing if the information sought appears reasonably calculated to lead to the discovery of admissible evidence.

(2) *Trial preparation materials.* A party may obtain discovery of documents and tangible things otherwise discoverable under subparagraph (1) of this paragraph and prepared in anticipation of or for the hearing by or for another party's representative (including his attorney, consultant, surety, indemnitor, insurer, or agent) only upon a showing that the party seeking discovery has substantial need of the materials in the preparation of his case and that he is unable without undue hardship to obtain the substantial equivalent of the materials by other means. In ordering discovery of such materials when the required showing has been made, the presiding officer shall protect against disclosure of the mental impressions, conclusions, opinions, or legal theories of an attorney or other representative of a party concerning the proceeding.

(c) *Protective order.* Upon motion by a party or the person from whom discovery is sought, and for good cause shown, the presiding officer may make any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense, including one or more of the following: (1) That the discovery not be had; (2) that the discovery may be had only on specified terms and conditions, including a designation of the time or place; (3) that the discovery may be had only by a method of discovery other than that selected by the party seeking discovery; (4) that certain matters not be inquired into, or that the scope of discovery be limited to certain matters; (5) that discovery be conducted with no one present except persons designated by the presiding officer; (6) that, subject to the provisions of §§ 2.744 and 2.790, a trade secret or other confidential research, development, or commercial information not be disclosed or be disclosed only in a designated way; (7) that studies and evaluations not be prepared. If the motion for a protective order is denied in whole or in part, the presiding officer may, on such terms and conditions as are just, order that any party or person provide or permit discovery.

(d) *Sequence and timing of discovery.* Unless the presiding officer upon motion, for the convenience of parties and witnesses and in the interests of justice, orders otherwise, methods of discovery may be used in any sequence and the fact that a party is conducting discovery, whether by deposition or otherwise, shall not operate to delay any other party's discovery.

(e) *Supplementation of responses.* A party who has responded to a request for discovery with a response that was complete when made is under no duty to supplement his response to include information thereafter acquired, except as follows:

(1) A party is under a duty seasonably to supplement his response with respect to any question directly addressed to (i) the identity and location of persons having knowledge of discoverable matters, and (ii) the identity of each person expected to be called as an expert witness at the hearing, the subject matter on which he is expected to testify, and the substance of his testimony.

(2) A party is under a duty seasonably to amend a prior response if he obtains information upon the basis of which (i) he knows that the response was incorrect when made, or (ii) he knows that the response though correct when made is no longer true and the circumstances are such that a failure to amend the response is in substance a knowing concealment.

(3) A duty to supplement responses may be imposed by order of the presiding officer or agreement of the parties.

(f) *Motion to compel discovery.* (1) If a deponent or party upon whom a request for production of documents or answers to interrogatories is served fails to respond or objects to the request, or any part thereof, or fails to permit inspection as requested, the deposing party or the party submitting the request may move the presiding officer, within ten (10) days after the date of the response or after failure of a party to respond to the request for an order compelling a response or inspection in accordance with the request. The motion shall set forth the nature of the questions or the request, the response or objection of the party upon whom the request was served, and arguments in support of the motion. For purposes of this paragraph, an evasive or incomplete answer or response shall be treated as a failure to answer or respond. Failure to answer or respond shall not be excused on the ground that the discovery sought is objectionable unless the person or party failing to answer or respond has applied for a protective order pursuant to paragraph (c) of this section.

(2) In ruling on a motion made pursuant to this section, the presiding officer may make such a protective order as he is authorized to make on a motion made pursuant to paragraph (c) of this section.

(3) This section does not preclude an independent request for issuance of a subpoena directed to a person not a party for production of documents and things. This section does not apply to requests for the testimony or interrogatories of the staff pursuant to § 2.720 (h) (2) or production of NRC documents pursuant to § 2.744 or § 2.790, except for paragraphs (c) and (e) of this section.

§ 2.740a Depositions upon oral examination and upon written interrogatories.

(a) Any party desiring to take the testimony of any party or other person by deposition on oral examination or written interrogatories shall, without leave of the Commission or the presiding officer, give reasonable notice in writing to every other party, to the person to be examined and to the presiding officer of the proposed time and place of taking the deposition; the name and address of each person to be examined, if known, or if, the name is not known, a general description sufficient to identify him or the class or group to which he belongs; the matters upon which each person will be examined and the name or descriptive title and address of the officer before whom the deposition is to be taken.

(b) [Deleted 37 FR 15127.]

(c) Within the United States, a deposition may be taken before any officer authorized to administer oaths by the laws of the United States or of the place where the examination is held. Outside of the United States, a deposition may be taken before a secretary of an embassy or legation, a consul general, vice consul or consular agent of the United States, or a person authorized to administer oaths designated by the Commission.

37 FR 15127

(d) The deponent shall be sworn or shall affirm before any questions are put to him. Examination and cross-examination shall proceed as at a hearing. Each question propounded shall be recorded and the answer taken down in the words of the witness. Objections on questions of evidence shall be noted in short form without the arguments. The officer shall not decide on the competency, materiality, or relevance of evidence but shall record the evidence subject to objection. Objections on questions of evidence not made before the officer shall not be deemed waived unless the ground of the objection is one which might have been obviated or removed if presented at that time.

27 FR 377

(e) When the testimony is fully transcribed, the deposition shall be submitted to the deponent for examination and signature unless he is ill or cannot be found or refuses to sign. The officer shall certify the deposition or, if the deposition is not signed by the deponent, shall certify the reasons for the failure to sign, and shall promptly forward the deposition by registered mail to the Commission.

43 FR 17798

(f) Where the deposition is to be taken on written interrogatories, the party taking the deposition shall serve a copy of the interrogatories, showing each interrogatory separately and consecutively numbered, on every other party with a notice stating the name and address of the person who is to answer them, and the name, description, title, and address of the officer before whom they are to be taken. Within ten (10) days after service, any other party may serve cross-interrogatories. The interrogatories, cross-interrogatories, and answers shall be recorded and signed, and the deposition certified, returned, and filed as in the case of a deposition on oral examination.

27 FR 377

(g) A deposition will not become a part of the record in the hearing unless received in evidence. If only part of a deposition is offered in evidence by a party, any other party may introduce any other parts. A party shall not be deemed to make a person his own witness for any purpose by taking his deposition.

(h) A deponent whose deposition is taken and the officer taking a deposition shall be entitled to the same fees as are paid for like services in the district courts of the United States, to be paid by the party at whose instance the deposition is taken.

(i) The witness may be accompanied, represented, and advised by legal counsel.

37 FR 15127

(j) The provisions of paragraphs (a) through (i) of this section are not applicable to NRC personnel. Testimony of NRC personnel by oral examination and written interrogatories addressed to NRC personnel are subject to the provisions of § 2.720(h).

§ 2.740b Interrogatories to parties.

(a) Any party may serve upon any other party (other than the staff)[6] written interrogatories to be answered in writing by the party served, or if the party served is a public or private corporation or a partnership or association, by any officer or agent, who shall furnish such information as is available to the party. A copy of the interrogatories, answers, and all related pleadings shall be filed with the Secretary of the Commission and shall be served on the presiding officer and upon all parties to the proceeding.

(b) Each interrogatory shall be answered separately and fully in writing under oath or affirmation, unless it is objected to, in which event the reasons for objection shall be stated in lieu of an answer. The answers shall be signed by the person making them, and the objections by the attorney making them. The party upon whom the interrogatories were served shall serve a copy of the answers and objections upon all parties to the proceeding within 14 days after service of the interrogatories, or within such shorter or longer period as the presiding officer may allow. Answers may be used in the same manner as depositions (see § 2.740a(g)).

§ 2.741 Production of documents and things and entry upon land for inspection and other purposes.

(a) *Request for discovery.* Any party may serve on any other party a request to:

(1) Produce and permit the party making the request, or a person acting on his behalf, to inspect and copy any designated documents, or to inspect and copy, test, or sample any tangible things which are within the scope of § 2.740 and which are in the possession, custody, or control of the party upon whom the request is served; or

(2) Permit entry upon designated land or other property in the possession or control of the party upon whom the request is served for the purpose of inspection and measuring, surveying photographing, testing, or sampling the property or any designated object or operation thereon, within the scope of § 2.740.

(b) *Service.* The request may be served on any party without leave of the Commission or the presiding officer. Except as otherwise provided in § 2.740, the request may be served after the proceeding is set for hearing.

(c) *Contents.* The request shall set forth the items to be inspected either by individual item or by category, and describe each item and category with reasonable particularity. The request shall specify a reasonable time, place, and manner of making the inspection and performing the related acts.

(d) *Response.* The party upon whom the request is served shall serve on the party submitting the request a written response within thirty (30) days after the service of the request. The response shall state, with respect to each item or category, that inspection and related activities will be permitted as requested, unless the request is objected to, in which case the reasons for objection shall be stated. If objection is made to part of an item or category, the part shall be specified.

37 FR 15127

(e) *NRC records and documents.* The provisions of paragraphs (a) through (d) of this section do not apply to the production for inspection and copying or photographing of NRC records or documents. Production of such records or documents is subject to the provisions of §§ 2.744 and 2.790.

§ 2.742 Admissions.

(a) Apart from any admissions made during or as a result of a prehearing conference, at any time after his answer has been filed, a party may file a written request for the admission of the genuineness and authenticity of any relevant document described in or attached to the request, or for the admission of the truth of any specified relevant matter of fact. A copy of the document shall be delivered with the request unless a copy has already been furnished.

27 FR 377

(b) Each requested admission shall be deemed made unless, within a time designated by the presiding officer or the Commission, and not less than ten (10) days after service of the request or such further time as may be allowed on motion, the party to whom the request is directed serves on the requesting party either (1) a sworn statement denying specifically the relevant matters of which an admission is requested or setting forth in detail the reasons why he can neither truthfully admit nor deny them, or (2) written objections on the ground that some or all of the matters involved are privileged or irrelevant or that the request is otherwise improper in whole or in part. Answers on matters to which such objections are made may be deferred until the objections are determined. If written objections are made to only a part of a request, the remainder of the request shall be answered within the time designated.

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[6] Interrogatories addressed to the staff are subject to § 2.720(h)(2)(ii).

(c) Admissions obtained pursuant to the procedure in this section may be used in evidence to the same extent and subject to the same objections as other admissions.

27 FR 377

§ 2.743 Evidence.

(a) *General.* Every party to a proceeding shall have the right to present such oral or documentary evidence and rebuttal evidence and conduct such cross-examination as may be required for full and true disclosure of the facts.

28 FR 10151

(b) *Written testimony.* The parties shall submit direct testimony of witnesses in written form, unless otherwise ordered by the presiding officer on the basis of objections presented. In any proceeding in which advance written testimony is to be used, each party shall serve copies of its proposed written testimony on each other party at least fifteen (15) days in advance of the session of the hearing at which its testimony is to be presented. The presiding officer may permit the introduction of written testimony not so served, either with the consent of all parties present or after they have had a reasonable opportunity to examine it. Written testimony shall be incorporated in the transcript of the record as if read or, in the discretion of the presiding officer, may be offered and admitted in evidence as an exhibit. This paragraph does not apply to proceedings under Subpart B for modification, suspension, or revocation of a license.

43 FR 17798

(c) *Admissibility.* Only relevant, material, and reliable evidence which is not unduly repetitious will be admitted. Immaterial or irrelevant parts of an admissible document will be segregated and excluded so far as is practicable.

(d) *Objections.* An objection to evidence shall breifly state the grounds of objection. The transcript shall include the objection, the grounds, and the ruling. Exception to an adverse ruling is preserved without notation on the record.

(e) *Offer of proof.* An offer of proof made in connection with an objection to a ruling of the presiding officer excluding or rejecting proffered oral testimony shall consist of a statement of the substance of the proffered evidence. If the excluded evidence is written, a copy shall be marked for identification. Rejected exhibits, adequately marked for identification, shall be retained in the record.

(f) *Exhibits.* A written exhibit will not be received in evidence unless the original and two copies are offered and a copy furnished to each party, or the parties have previously been furnished with copies or the presiding officer directs otherwise. The presiding officer may permit a party to replace with a true copy an original document admitted in evidence.

27 FR 377

(g) *Proceedings involving applications.* In any proceeding involving an application, there shall be offered in evidence by the staff any report submitted by the ACRS in the proceeding in compliance with section 182b. of the Act, any safety evaluation prepared by the staff and any environmental impact statement prepared by the Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards as appropriate, or his designee in the proceeding pursuant to Subpart A of Part 51 of this chapter.

49 FR 9352

(h) *Official record.* An official record of a government agency or entry in an official record may be evidenced by an official publication or by a copy attested by the officer having legal custody of the record and accompanied by a certificate of his custody.

27 FR 377

(i) *Official notice.* (1) the Commission or the presiding officer may take official notice of any fact of which a court of the United States may take judicial notice or of any technical or scientific fact within the knowledge of the Commission as an expert body. Each fact officially noticed under this subparagraph shall be specified in the record with sufficient particularity to advise the parties of the matters which have been noticed or brought to the attention of the parties before final decision and each party adversely affected by the decision shall be given opportunity to controvert the fact.

37 FR 15127

(2) If a decision is stated to rest in whole or in part on official notice of a fact which the parties have not had a prior opportunity to controvert, a party may controvert the fact by filing an appeal from an initial decision or a petition for reconsideration of a final decision clearly and concisely setting forth the information relied upon to show the contrary.

48 FR 52282

§ 2.744 Production of NRC records and documents.

37FR15127

(a) A request for the production of an NRC record or document not available pursuant to § 2.790 by a party to an initial licensing proceeding may be served on the Executive Director for Operations without leave of the Commission or the presiding officer. The request shall set forth the records or documents requested, either by individual item or by category, and shall describe each item or category with reasonable particularity and shall state why that record or document is relevant to the proceeding.

(b) If the Executive Director for Operations objects to producing a requested record or document on the grounds that (1) it is not relevant or (2) it is exempted from disclosure under § 2.790 and the disclosure is not necessary to a proper decision in the proceeding or the document or the information therein is reasonably obtainable from another source, he shall so advise the requesting party.

(c) If the Executive Director for Operations objects to producing a record or document, the requesting party may apply to the presiding officer, in writing, to compel production of that record or document. The application shall set forth the relevancy of the record or document to the issues in the proceeding. The application shall be processed as a motion in accordance with § 2.730(a) through (d). The record or document covered by the application shall be produced for the "in camera" inspection of the presiding officer, exclusively, if requested by the presiding officer and only to the extent necessary to determine—

(1) The relevancy of that record or document;

(2) Whether the document is exempt from disclosure under § 2.790;

(3) Whether the disclosure is necessary to a proper decision in the proceeding;

(4) Whether the document or the information therein is reasonably obtainable from another source.

37 FR 15127

(d) Upon a determination by the presiding officer that the requesting party has demonstrated the relevancy of the record or document and that its production is not exempt from disclosure under § 2.790 or that, if exempt, its disclosure is necessary to a proper decision in the proceeding, and the document or the information therein is not reasonably obtainable from another source, he shall order the Executive Director for Operations to produce the document.

40 FR 2973

(e) In the case of requested documents and records (including Safeguards Information referred to in sections 147 and 181 of the Atomic Energy Act, as amended) exempt from disclosure under § 2.790, but whose disclosure is found by the presiding officer to be necessary to a proper decision in the proceeding, any order to the Executive Director for Operations to produce the document or records (or any other order issued ordering production of the document or records) may contain such protective terms and conditions (including affidavits of non-disclosure) as may be necessary and appropriate to limit the disclosure to parties in the proceeding, to interested States and other governmental entities participating pursuant to § 2.715(c), and to their qualified witnesses and counsel. When Safeguards Information protected from disclosure under section 147 of the Atomic Energy Act, as amended, is received and possessed by a party other than the Commission staff, it shall also be protected according to the requirements of § 73.21 of this chapter. The presiding officer may also prescribe such additional procedures as will effectively safeguard and prevent disclosure of Safeguards Information to unauthorized persons with minimum impairment of the procedural rights which would be available if Safeguards Information were not involved. In addition to any other sanction that may be imposed by the presiding officer for violation of an order issued pursuant to this paragraph, violation of an order pertaining to the disclosure of Safeguards Information protected from disclosure under section 147 of the Atomic Energy Act, as amended, may be subject to a civil penalty imposed pursuant to § 2.205. For the purpose of imposing the criminal penalties contained in section 223 of the Atomic Energy Act, as amended, any order issued pursuant to this paragraph with respect to Safeguards Information shall be deemed an order issued under section 161b of the Atomic Energy Act.

46 FR 51718

(f) A ruling by the presiding officer, the Atomic Safety and Licensing Appeal Board, or the Commission for the production of a record or document will specify the time, place, and manner of production.

37 FR 15127

(g) No request pursuant to this section shall be made or entertained before the matters in controversy have been identified by the Commission or the presiding officer, or after the beginning of the prehearing conference held pursuant to § 2.752 except upon leave of the presiding officer for good cause shown.

40 FR 2973

(h) The provisions of § 2.740 (c) and (e) shall apply to production of NRC records and documents pursuant to this section.

SUMMARY DISPOSITION ON PLEADINGS

37 FR 15127

§ 2.749 Authority of presiding officer to dispose of certain issues on the pleadings.

(a) Any party to a proceeding may move, with or without supporting affidavits, for a decision by the presiding officer in that party's favor as to all or any part of the matters involved in the proceeding. There shall be annexed to the motion a separate, short and concise statement of the material facts as to which the moving party contends that there is no genuine issue to be heard. Motions shall be filed within such time as may be fixed by the presiding officer. Any other party may serve an answer supporting or opposing the motion, with or without affidavits, within twenty (20) days after service of the motion. There shall be annexed to any answer opposing the motion a separate, short and concise statement of the material facts as to which it is contended that there exists a genuine issue to be heard. All material facts set forth in the statement required to be served by the moving party will be deemed to be admitted unless controverted by the statement required to be served by the opposing party. The opposing party may within ten days after service respond in writing to new facts and arguments presented in any statement filed in support of the motion. No further supporting statements or responses thereto shall be entertained. The board may dismiss summarily motions filed shortly before the hearing commences or during the hearing if the other parties or the board would be required to divert substantial resources from the hearing in order to respond adequately to the motion.

46 FR 30328

(b) Affidavits shall set forth such facts as would be admissible in evidence and shall show affirmatively that the affiant is competent to testify to the matters stated therein. The presiding officer may permit affidavits to be supplemented or opposed by depositions, answers to interrogatories or further affidavits. When a motion for summary decision is made and supported as provided in this section, a party opposing the motion may not rest upon the mere allegations or denials of his answer; his answer by affidavits or as otherwise provided in this section must set forth specific facts showing that there is a genuine issue of fact. If no such answer is filed, the decision sought, if appropriate, shall be rendered.

(c) Should it appear from the affidavits of a party opposing the motion that he cannot, for reasons stated, present by affidavit facts essential to justify his opposition, the presiding officer may refuse the application for summary decision or may order a continuance to permit affidavits to be obtained or make such other order as is appropriate and a determination to that effect shall be made a matter of record.

(d) The presiding officer shall render the decision sought if the filings in the proceeding, depositions, answers to interrogatories, and admissions on file, together with the statements of the parties and the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a decision as a matter of law. However, if any proceeding involving a construction permit for a production or utilization facility, the procedure described in this section may be used only for the determination of specific subordinate issues and may not be used to determine the ultimate issue as to whether the permit shall be issued.

37 FR 15127

HEARINGS

§ 2.750 Official reporter; transcript.

(a) A hearing will be reported under the supervision of the presiding officer, stenographically or by other means, by an official reporter who may be designated from time to time by the Commission or may be a regular employee of the Commission. The transcript prepared by the reporter shall be the sole official transcript of the proceeding. Except as limited pursuant to Section 181 of the Act

27 FR 377

27 FR 377

or order of the Commission, the transcript will be open for inspection at the Public Document Room. Copies of transcripts are available to parties and to the public from the official reporter on payment of the charges fixed therefor.

(b) Transcript corrections: Corrections of the official transcript may be made only in the manner provided by this paragraph. Corrections ordered or approved by the presiding officer shall be included in the record as an appendix, and when so incorporated the Secretary shall make the necessary physical corrections in the official transcript so that it will incorporate the changes ordered. In making corrections there shall be no substitution of pages but, to the extent practicable, corrections shall be made by running a line through the matter to be changed without obliteration and writing the matter as changed immediately above. Where the correction consists of an insertion, it shall be added by rider or interlineation as near as possible to the text which is intended to precede and follow it.

45 FR 49535

(c) Free transcript: Except in an antitrust proceeding, in any adjudicatory proceeding on an application for a license or an amendment thereto, the presiding officer may arrange for provision of one free transcript to a party, other than the applicant, upon request by that party. The transcript will be made available to a party at the same time and location as it is made available to the NRC staff. If a transcript is mailed to the staff, it will also be mailed to the requesting party. A presiding officer has the discretion to control the distribution of transcripts to parties. [1]*

27 FR 377

§ 2.751 Hearings to be public.

Except as may be requested pursuant to Section 181 of the Act, all hearings will be public unless otherwise ordered by the Commission.

37 FR 15127

§ 2.751a Special prehearing conference in construction permit and operating license proceedings.

43 FR 17798

(a) In any proceeding involving an application for a construction permit or an operating license for a production or utilization facility, the Commission or the presiding officer will direct the parties and any petitioners for intervention, or their counsel, to appear at a specified time and place, within ninety (90) days after the notice of hearing is published, or such other time as the Commission or the presiding officer may deem appropriate, for a conference[7] to:

37 FR 15127

(1) Permit identification of the key issues in the proceeding;

(2) Take any steps necessary for further identification of the issues;

(3) Consider all intervention petitions to allow the presiding officer to make such preliminary or final determination as to the parties to the proceeding, as may be appropriate; and

(4) Establish a schedule for further actions in the proceeding.

(b) The presiding officer may order any further informal conferences among the parties, including telephone conferences, to the extent that he considers that such a conference would expedite the proceeding.

(c) A prehearing conference held pursuant to this section may be stenographically reported.

46 FR 30328

(d) The presiding officer shall enter an order which recites the action taken at the conference, the schedule for further actions in the proceeding, any agreements by the parties, and which identifies the key issues in the proceeding, makes a preliminary or final determination as to the parties in the proceeding, and provides for the submission of status reports on discovery. The order shall be served upon all parties to the proceeding. Objections to the order may be filed by a party within five (5) days after service of the order, except that the staff may file objections to such order within ten (10) days after service. Parties may not file replies to the objections unless the Board so directs. The filing of objections shall not stay the decision unless the presiding officer so orders. The board may revise the order in consideration of the objections presented and, as permitted by § 2.718(i), may certify for determination to the Commission or the Atomic Safety and Licensing Appeal Board, as appropriate, such matters raised in the objections as it deems appropriate. The order shall control the subsequent course of the proceeding unless modified for good cause.

46 FR 30328

40 FR 8774

§ 2.752 Prehearing conference.

(a) The Commission or the presiding officer may, and in the case of a proceeding on an application for a construction permit or an operating license for a facility of a type described in §§ 50.21(b) or 50.22 of this chapter or a testing facility, shall direct the parties or their counsel to appear at a specified time and place for a conference to consider:

(1) Simplification, clarification, and specification of the issues;

(2) The necessity or desirability of amending the pleadings;

(3) The obtaining of stipulations and admissions of fact and of the contents and authenticity of documents to avoid unnecessary proof;

(4) Identification of witnesses and the limitation of the number of expert witnesses, and other steps to expedite the presentation of evidence;

(5) The setting of a hearing schedule; and

(6) Such other matters as may aid in the orderly disposition of the proceeding.

A prehearing conference held under this section in a proceeding involving a construction permit or operating license shall be held within sixty (60) days after discovery has been completed,[8] or such other time as the Commission or the presiding officer may specify.

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* [1] This paragraph is suspended until further action of the Commission. 46 FR 13681

[7] This conference may be omitted in proceedings other than contested proceedings.

[8] Discovery, as used in this section, does not include the production of the ACRS report, the safety evaluation prepared by the regulatory staff, or any detailed statement on environmental considerations prepared by the Director of Regulation or his designee in the proceeding pursuant to Appendix D of Part 50 of this chapter.

27 FR 377

(b) Prehearing conferences may be stenographically reported.

46 FR 30328

(c) The presiding officer shall enter an order which recites the action taken at the conference, the amendments allowed to the pleadings and agreements by the parties, and which limits the issues or defines the matters in controversy to be determined in the proceeding. Objections to the order may be filed by a party within five (5) days after service of the order, except that the regulatory staff may file objections to such order within ten (10) days after service. Parties may not file replies to the objections unless the board so directs. The filing of objections shall not stay the decision unless the presiding officer so orders. The board may revise the order in the light of the objections presented and, as permitted by § 2.718(i) may certify for determination to the Commission or the Atomic Safety and Licensing Appeal Board, as appropriate, such matters raised in the objections as it deems appropriate. The order shall control the subsequent course of the proceeding unless modified for good cause.

37 FR 15127

§ 2.753 Stipulations.

Apart from any stipulations made during or as a result of a prehearing conference, the parties may stipulate in writing at any stage of the proceeding or orally during the hearing, any relevant fact or the contents or authenticity of any document. Such a stipulation may be received in evidence. The parties may also stipulate as to the procedure to be followed in the proceeding. Such stipulations may, on motion of all parties, be recognized by the presiding officer to govern the conduct of the proceeding.

46 FR 30328

§ 2.754 Proposed findings and conclusions.

(a) Any party to a proceeding may, or if directed by the presiding officer shall, file proposed findings of fact and conclusions of law, briefs and a proposed form or order of decision within the time provided by the following subparagraphs, except as otherwise ordered by the presiding officer:

(1) The party who has the burden of proof shall, within thirty (30) days after the record is closed, file proposed findings of fact and conclusions of law and briefs, and a proposed form of order or decision.

(2) Other parties may file proposed findings, conclusions of law and briefs within forty (40) days after the record is closed. However, the staff may file such proposed findings, conclusions of law and briefs within fifty (50) days after the record is closed.

(3) A party who has the burden of proof may reply within five (5) days after filing of proposed findings and conclusions of law and briefs by other parties.

43 FR 17798

(b) Failure to file proposed findings of fact, conclusions of law or briefs when directed to do so may be deemed a default, and an order or initial decision may be entered accordingly.

27 FR 377

(c) Proposed findings of fact shall be clearly and concisely set forth in numbered paragraphs and shall be confined to the material issues of fact presented on the record, with exact citations to the transcript of record and exhibits in support of each proposed finding. Proposed conclusions of law shall be set forth in numbered paragraphs as to all material issues of law or discretion presented on the record. Proposed findings of fact and conclusions of law submitted by a person who does not have the burden of proof and who has only a limited interest in the proceeding may be confined to matters which affect his interests.

§ 2.755 Oral argument before presiding officer.

When, in the opinion of the presiding officer, time permits and the nature of the proceeding and the public interest warrant, he may allow and fix a time for the presentation of oral argument. He will impose appropriate limits of time on the argument. The transcript of the argument shall be a part of the record.

35 FR 11459

§ 2.756 Informal procedures.

The Commission encourages the use of informal procedures consistent with the Act, sections 551-558 of title 5 of the United States Code, and the regulations in this chapter, and with the orderly conduct of the proceeding and the necessity for preserving a suitable record for review.

37 FR 15127

§ 2.757 Authority of presiding officer to regulate procedure in a hearing.

To prevent unnecessary delays or an unnecessarily large record, the presiding officer may:

(a) Limit the number of witnesses whose testimony may be cumulative;

(b) Strike argumentative, repetitious, cumulative, or irrelevant evidence;

(c) Take necessary and proper measures to prevent argumentative, repetitious, or cumulative cross-examination; and

(d) Impose such time limitations on arguments as he determines appropriate, having regard for the volume of the evidence and the importance and complexity of the issues involved.

§ 2.758 Consideration of Commission rules and regulations in adjudicatory proceedings.

(a) Except as provided in paragraphs (b), (c), and (d) of this section, any rule or regulation of the Commission, or any provision thereof, issued in its program for the licensing and regulation of production and utilization facilities, source material, special nuclear material or by-product material, shall not be subject to attack by way of discovery, proof, argument, or other means in any adjudicatory proceeding involving initial licensing subject to this subpart, other than a pending proceeding wherein a party has attacked such rule or regulation, and the presiding officer, the Atomic Safety and Licensing Appeal Board or the Commission has ruled thereon before August 27, 1972.**

**Effective date of these amendments.

(b) A party to an adjudicatory proceeding involving initial licensing subject to this subpart may petition that the application of a specified Commission rule or regulation or any provision thereof, of the type described in paragraph (a) of this section, be waived or an exception made for the particular proceeding. The sole ground for petition for waiver or exception shall be that special circumstances with respect to the subject matter of the particular proceeding are such that application of the rule or regulation (or provision thereof) would not serve the purposes for which the rule or regulation was adopted. The petition shall be accompanied by an affidavit that identifies the specific aspect or aspects of the subject matter of the proceeding as to which application of the rule or regulation (or provision thereof) would not serve the purposes for which the rule or regulation was adopted, and shall set forth with particularity the special circumstances alleged to justify the waiver or exception requested. Any other party may file a response thereto, by counter-affidavit or otherwise.

(c) If, on the basis of the petition, affidavit and any response thereto provided for in paragraph (b) of this section, the presiding officer determines that the petitioning party has not made a prima facie showing that the application of the specific Commission rule or regulation or provision thereof to a particular aspect or aspects of the subject matter of the proceeding would not serve the purposes for which the rule or regulation was adopted and that application of the rule or regulation should be waived or an exception granted, no evidence may be received on that matter and no discovery, cross-examination or argument directed to the matter will be permitted, and the presiding officer may not further consider the matter.

(d) If, on the basis of the petition, affidavit and any response provided for in paragraph (b) of this section, the presiding officer determines that such a prima facie showing has been made, the presiding officer shall, before ruling thereon, certify directly to the Commission[7] for determination the matter of whether the application of the Commission rule or regulation or provision thereof to a particular aspect or aspects of the subject matter of the proceeding, in the context of this section, should be waived or an exception made. The Commission may, among other things, on the basis of the petition, affidavits, and any response, determine whether the application of the specified rule or regulation (or provision thereof) should be waived or an exception be made, or the Commission may direct such further proceedings as it deems appropriate to aid its determination.

37 FR 15127

(e) Whether or not the procedure in paragraph (b) of this section is available, a party to an initial licensing proceeding may file a petition for rule making pursuant to § 2.802.

§ 2.759 Settlement in initial licensing proceedings.

The Commission recognizes that the public interest may be served through settlement of particular issues in a proceeding or the entire proceeding. Therefore, to the extent that it is not inconsistent with hearing requirements in section 189 of the Act (42 U.S.C. 2239), the fair and reasonable settlement of contested initial licensing proceedings is encouraged. It is expected that the presiding officer and all of the parties to those proceedings will take appropriate steps to carry out this purpose.

37 FR 15127

INITIAL DECISION AND COMMISSION REVIEW

§ 2.760 Initial decision and its effect.

31 FR 4339

§ 2.760 Initial decision and its effect.

(a) After hearing, the presiding officer will render an initial decision which will constitute the final action of the Commission forty-five (45) days after its date when it authorizes the issuance or amendment of a license or limited work authorization for a facility, or thirty (30) days after its date in any other case, unless an appeal is taken in accordance with § 2.762 or the Commission directs that the record be certified to it for final decision.

(b) Where the public interest so requires, the Commission may direct that the presiding officer certify the record to it without an initial decision, and may—

(1) Prepare its own initial decision, which will become final unless a notice of appeal is filed; or

48 FR 52282

(2) Omit an initial decision on a finding that due and timely execution of its functions imperatively and unavoidably so requires.

(c) An initial decision will be in writing and will be based on the whole record and supported by reliable, probative, and substantial evidence. The initial decision will include:

(1) Findings, conclusions and rulings, with the reasons or basis for them, on all material issues of fact, law, or discretion presented on the record;

(2) All facts officially noticed and relied on in making the decision;

27 FR 377

(3) The appropriate ruling, order or denial of relief with the effective date;

31 FR 4339

(4) The time within which a notice of appeal from the decision and a supporting brief may be filed, the time within which briefs in support of or in opposition to an appeal filed by another party may be filed and, in the case of an initial decision which may become final in accordance with paragraph (a) of this section, the date when it may become final.

48 FR 52282

§ 2.760a Initial decision in contested proceedings on applications for facility operating licenses.

In any initial decision in a contested proceeding on an application for an operating license for a production or utilization facility, the presiding officer shall make findings of fact and conclusions of law on the matters put into controversy by the parties to the proceeding and on matters which have been determined to be the issues in the proceeding by the Commission or the presiding officer. Matters not put into controversy by the parties will be examined and decided by the presiding officer only where he or she determines that a serious safety, environmental, or common defense and security matter exists. Depending on the resolution of those matters, the Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate, after making the requisite findings, will issue, deny, or appropriately condition the license.

44 FR 67088

§ 2.761 Expedited decisional procedure.

(a) The presiding officer may determine a proceeding by an order after the conclusion of a hearing without issuing an initial decision, when:

27 FR 377

(1) All parties stipulate that the initial decision may be omitted and waived their rights to file a notice of appeal, to request oral argument, and to seek judicial review;

48 FR 52282

(2) No unresolved substantial issue of fact, law, or discretion remains, and the record clearly warrants granting the relief requested; and

(3) The presiding officer finds that dispensing with the issuance of the initial decision is in the public interest.

27 FR 377

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[7] The matter will be certified to the Commission notwithstanding the provisions of § 2.785.

27 FR 377

(b) An order entered pursuant to paragraph (a) of this section shall be subject to review by the Commission on its own motion within thirty (30) days after its date.

28 FR 10151

(c) An initial decision may be made effective immediately, subject to review by the Commission on its own motion within thirty (30) days after its date, except as otherwise provided in this chapter when:

48FR52282

(1) All parties stipulate that the initial decision may be made effective immediately and waive their rights to file a notice of appeal, to request oral argument, and to seek judicial review;

27 FR 377

(2) No unresolved substantial issue of fact, law, or discretion remains and the record clearly warrants granting the relief requested; and

(3) The presiding officer finds that it is in the public interest to make the initial decision effective immediately.

35 FR 5317

(d) The provisions of this section do not apply to an initial decision directing the issuance or amendment of a construction permit or construction authorization, or the issuance of an operating license or provisional operating authorization.

49 FR 9352

§ 2.761a Separate hearings and decisions.

In a proceeding on an application for a construction permit for a utilization facility which is subject to § 51.20(b) of this chapter, and is of the type specified in §§ 51.21(b) (2) or (3) or 50.22 of this chapter or is a testing facility, the presiding officer shall unless the parties agree otherwise or the rights of any party would be prejudiced thereby, commence a hearing on issues covered by § 50.10(e)(2)(ii) and Subpart A of Part 51 of this chapter as soon as practicable after issuance of the staff of its final environmental impact statement, but no later than thirty (30) days after issuance of such statement, and complete such a hearing and issue an initial decision on such matters. Pehearing procedures regarding issues covered by Subpart A of Part 51 and § 51.10(e)(2)(ii) of this chapter, including any discovery and special prehearing conferences and prehearing conferences as provided in §§ 2.740, 2.740a, 2.740b, 2.741, 2.742, 2.751a, and 2.752, shall be scheduled accordingly. The provisions of §§ 2.754, 2.755, 2.760, 2.762, 2.763, and 2.764(a) shall apply to any proceeding conducted and any initial decision rendered in accordance with this section. Paragraph 2.764(b) shall not apply to any partial initial decision rendered in accordance with this section. This section shall not preclude separate hearings and decisions on other particular issues.

48 FR 52282

§ 2.762 Appeals to the Commission from initial decisions.

(a) *Notice of Appeal.* Within ten (10) days after service of an initial decision, any party may take an appeal to the Commission by filing a notice of appeal. The notice shall specify—

(1) the party taking the appeal; and

(2) the decision being appealed.

(b) *Filing Appellant's Brief.* Each appellant shall file a brief supporting its position on appeal within thirty (30) days (40 days if Commission staff is the appellant) after the filing of notice required by paragraph (a) of this section.

(c) *Filing Responsive Brief.* Any party who is not an appellant may file a brief in support of or in opposition to the appeal within thirty (30) days after the period has expired for the filing and service of the brief of all appellants. Commission staff may file a responsive brief within forty (40) days after the period has expired for the filing and service of the briefs of all appellants. A responding party shall file a single responsive brief regardless of the number of appellants' briefs filed.

(d) *Brief Content.* A brief in excess of ten (10) pages shall contain a table of contents, with page references, and a table of cases (alphabetically arranged), statutes, regulations, and other authorities cited, with references to the pages of the brief where they are cited.

(1) An appellant's brief must clearly identify the errors of fact or law that are the subject of the appeal. For each issue appealed, the precise portion of the record relied upon in support of the assertion of error must also be provided.

(2) Each responsive brief must contain a reference to the precise portion of the record which supports each factual assertion made.

(e) *Brief Length.* A party shall not file a brief in excess of seventy (70) pages in length, exclusive of pages containing the table of contents, table of citations and any addendum containing statutes, rules, regulations, etc. A party may request an increase of this page limit for good cause. Such a request shall be made by motion submitted at least seven (7) days before the date upon which the brief is due for filing and shall specify the enlargement requested.

(f) *Certificate of Service.* All documents filed under this section must be accompanied by a certificate reflecting service upon all other parties to the proceeding.

(g) *Failure to Comply.* A brief which in form or content is not in substantial compliance with the provisions of this section may be stricken, either on motion of a party or by the Commission on it own initiative.

48 FR 52282

§ 2.763 Oral argument.

In its discretion the Commission may allow oral argument upon the request of a party made in a notice of appeal or brief, or upon it own initiative.

§ 2.764 Immediate effectiveness of initial decision directing issuance or amendment of construction permit or operating license.

(a) Except as provided in paragraphs (c) through (f) of this section, or as otherwise ordered by the Commission in special circumstances, an initial decision directing the issuance or amendment of a construction permit, a construction authorization, or an operating license shall be effective immediately upon issuance unless the presiding officer finds that good cause has been shown by a party why the initial decision should not become immediately effective, subject to the review thereof and further decision by the Commission upon notice of appeal filed by any party pursuant to § 2.762 or upon its own motion.

(b) Except as provided in paragraphs (c) through (f) of this section, or as otherwise ordered by the Commission in special circumstances, the Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate, notwithstanding the filing of a notice of appeal, shall issue a construction permit, a construction authorization, or an operating license, or amendments thereto, authorized by an initial decision, within ten (10) days from the date of issuance of the decision.

5 FR 74693 **(c) An initial decision directing the issuance of an initial license for the construction and operation of an independent spent fuel storage installation (ISFSI) under 10 CFR Part 72 of this chapter shall not become effective until review by the Commission has been completed. The Director of Nuclear Material Safety and Safeguards shall not issue an initial license for the construction and operation of an independent spent fuel storage installation (ISFSI) under 10 CFR Part 72 of this chapter until expressly authorized to do by the Commission.**

46 FR 13971 **(d) An initial decision directing the issuance of a construction authorization or license under Part 60 of this chapter (relating to disposal of high-level radioactive wastes in geologic repositories) or any amendment to such an authorization or a license authorizing actions which may significantly affect the health and safety of the public, shall become effective only upon order of the Commission. The Director of Nuclear Material Safety and Safeguards shall not issue a construction authorization or a license under Part 60 of this chapter,** or any amendment to such an authorization or license which may significantly affect the health and safety of the public until expressly authorized to do so by the Commission.

46 FR 47764 (e) *Nuclear power reactor construction permits*

46 FR 28627 (1) Atomic Safety and Licensing Boards

(i) Atomic Safety and Licensing Boards shall hear and decide all issues that come before them, indicating in their decisions the type of licensing action, if any, which their decision would authorize. The Boards' decisions concerning construction permits shall not become effective until the Appeal Board and Commission actions outlined below in paragraphs (2) and (3) have taken place.

47 FR 2286 **(ii) In reaching their decisions the Boards should interpret existing regulations and regulatory policies with due consideration to the implications for those regulations and policies of the Three Mile Island accident. As provided in paragraph (e)(3) of this section, in addition to taking generic rulemaking actions, the Commission will be providing case-by-case guidance on changes in regulatory policies in conducting its reviews in adjudicatory proceedings. The Boards shall, in turn, apply these revised regulations and policies in cases then pending before them to the extent that they are applicable. The Commission expects the Licensing Boards to pay particular attention in their decisions to analyzing the evidence on those safety and environmental issues arising under applicable Commission regulations and policies which the Boards believe present serious, close questions and which the Boards believe may be crucial to whether a license should become effective before full appellate review is completed. Furthermore, the Boards should identify any apects of the case which in their judgment, present issues on which prompt Commission policy guidance is called for. The Boards may request the assistance of the parties in identifying such policy issues but, absent specific Commission directives, such policy issues shall not be the subject of discovery, examination, or cross-examination.**

46 FR 28627 (2) Atomic Safety and Licensing Appeal Boards

(i) Within sixty days of the service of any Licensing Board decision that would otherwise authorize issuance of a construction permit, the Appeal Board shall decide any stay motions that are timely filed.[1] For the purpose of this policy, a "stay" motion is one that seeks to defer the effectiveness of a Licensing Board decision beyond the period necessary for the Appeal Board and Commission action described herein. If no stay papers are filed, the Appeal Board shall, within the same time period (or earlier if possible), analyze the record and construction permit decision below on its own motion and decide whether a stay is warranted. It shall not, however, decide that a stay is warranted without giving the affected parties an opportunity to be heard.

(ii) In deciding these stay questions, the Appeal Board shall employ the procedures set out in 10 CFR 2.788. However, in addition to the factors set out in 10 CFR 2.788(e), the Board will give particular attention to whether issuance of the permit prior to full administrative review may: (A) Create novel safety or environmental issues in light of the Three Mile Island accident; or (B) prejudice review of significant safety or environmental issues. In addition to deciding the stay issue, the Appeal Board will inform the Commission if it believes that the case raises issues on which prompt Commission policy guidance, particularly guidance on possible changes to present Commission regulations and policies, would advance the Board's appellate review. If the Appeal Board is unable to issue a decision within the sixty-day period, it should explain the cause of the delay to the Commission. The Commission shall thereupon either allow the Appeal Board the additional time necessary to complete its task or take other appropriate action, including taking the matter over itself. The running of the sixty-day period shall not operate to make the Licensing Board decision effective. Unless otherwise ordered by the Commission, the Appeal Board will conduct its normal appellate review of the Licensing Board decision after it has issued its decision on any stay request.

46 FR 28627 (3) Commission

(i) Reserving to itself the right to step in at any earlier stage of the proceeding, the Commission will, upon receipt of the Appeal Board decision on whether the effectiveness of a Licensing Board construction permit decision should be further delayed, review the matter on its own motion, applying the same criteria. The parties shall have no right to file pleadings with the Commission with regard to the Appeal Board's stay decision unless requested to do so.

(ii) The Commission will seek to issue a decision in each construction permit case within 20 days of receipt of the Appeal Board's stay decision. If the Commission does not act finally within that time, it will state the reason for its further consideration and indicate that time it anticipates will be required to reach its decision. In such an event, if the Appeal Board has not stayed the Licensing Board's decision, the initial decision will be considered stayed pending the Commission's decision.

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[1] Such motions shall be filed as provided by 10 CFR 2.788. No request need be filed with the Licensing Board prior to filing with the Appeal Board. Cf. Public Service Company of New Hampshire (Seabrook Station, Units 1 and 2), ALAB-338, 4 NRC 10 (1976). The sixty-day period has been selected in recognition of two facts: first, allowing time for service by mail, close to thirty days may elapse before the Appeal Board has all the stay papers before it; second, the Appeal Board may find it necessary to hold oral argument.

(iii) In announcing the result of its review of any Appeal Board stay decision, the Commission may allow the proceeding to run its ordinary course or give whatever instructions as to the future handling of the proceeding it deems appropriate (for example, it may direct the Appeal Board to review the merits of particular issues in expedited fashion; furnish policy guidance with respect to particular issues; or decide to review the merits of particular issues itself, bypassing the Appeal Board).

47 FR 2286

(f) *Nuclear power reactor operating licenses*—(1) *Atomic Safety and Licensing Boards.* (i) Atomic Safety and Licensing Boards shall hear and decide all issues that come before them, indicating in their decisions the type of licensing action, if any, which their decision would authorize. A Board's decision authorizing issuance of an operating license (including a fuel loading and low power testing license) shall not become effective insofar as it authorizes operating at greater than 5 percent of rated power until the Commission actions outlined below in paragraph (f)(2) of this section have taken place. Insofar as it authorizes operation up to 5 percent, the decision shall become effective and the Director shall issue the appropriate license in accordance with paragraph (b) of this section.

46 FR 47764

(ii) In reaching their decisions the Boards should interpret existing regulations and regulatory policies with due consideration to the implications for those regulations and policies of the Three Mile Island accident. In this regard it should be understood that as a result of analyses still under way the Commission may change its present regulations and regulatory policies in important respects and thus compliance with existing regulations may turn out to no longer warrant approval of a license application. As provided in paragraph (f)(2) of this section, in addition to taking generic rulemaking actions, the Commission will be providing case-by-case guidance on changes in regulatory policies in conducting its reviews in adjudicatory proceedings. The Boards shall, in turn, apply these revised regulations and policies in cases then pending before them to the extent that they are applicable. The Commission expects the Licensing Boards to pay particular attention in their decisions to analyzing the evidence on those safety and environmental issues arising under applicable Commission regulations and policies which the Boards believe present serious, close questions and which the Boards believe may be crucial to whether a license should become effective before full appellate review is completed. Furthermore, the Boards should identify any aspects of the case which in their judgment, present issues on which prompt Commission policy guidance is called for. The Boards may request the assistance of the parties in identifying such policy issues but, absent specific Commission directive, such policy issues shall not be the subject of discovery, examination, or cross-examination.

46 FR 28627

(2) *Commission.* (i) Reserving the power to step in at an earlier time, the Commission will, upon receipt of the Licensing Board decision authorizing issuance of an operating license, other than a decision authorizing only fuel loading and low power (up to 5 percent of rated power) testing, review the matter on its own motion to determine whether to stay the effectiveness of the decision. An operating license decision will be stayed by the Commission, insofar as it authorizes other than fuel loading and low power testing, if it determines that it is in the public interest to do so, based on a consideration of the gravity of the substantive issue, the likelihood that it has been resolved incorrectly below, the degree to which correct resolution of the issue would be prejudiced by operation pending review, and other relevant public interest factors.

(ii) For operating license decisions other than those authorizing only fuel loading and low power testing consistent with the target schedule set forth below, the parties may file brief comments with the Commission pointing out matters which, in their view, pertain to the immediate effectiveness issue. To be considered, such comments must be received within 10 days of the Board decision. However, the Commission may dispense with comments by so advising the parties. No extensive stay shall be issued without giving the affected parties an opportunity to be heard.

(iii) The Commission intends to issue a stay decision within 30 days of receipt of the Licensing Board's decision. The Licensing Board's initial decision will be considered stayed pending the Commission's decision insofar as it may authorize operations other than fuel loading and low power (up to 5 percent of rated power) testing.

(iv) In announcing a stay decision, the Commission may allow the proceeding to run its ordinary course or give instructions as to the future handling of the proceeding (for example, it may direct the Appeal Board to review the merits of particular issues in expedited fashion; furnish policy guidance with respect to particular issues; or decide to review the merits of particular issues itself, bypassing the Appeal Board). Furthermore, the Commission may in a particular case determine that compliance with existing regulations and policies may not longer be sufficient to warrant approval of a license application and may alter those regulations and policies.

46 FR 47764

(g) Unless the Commission otherwise explicitly so directs in its immediate effectiveness determination, no comment made in the course of the opinion or statement reflecting that determination is to be given any weight by the Atomic Safety and Licensing Board or Appeal Board in its consideration of either a stay motion pursuant to § 2.788(e) or an appeal on the merits pursuant to §§ 2.762 and 2.785, or in any subsequent formal adjudication. The Commission's effectiveness determination is entirely without prejudice to such consideration in subsequent proceedings.

47 FR 40535

§ 2.765 Immediate effectiveness of initial decision directing issuance or amendment of licenses under Part 61 of this chapter.

An initial decision directing the issuance of a license under Part 61 of this chapter (relating to land disposal of radioactive waste) or any amendment to such a license authorizing actions which may significantly affect the health and safety of the public, will become effective only upon order of the Commission. The Director of Nuclear Material Safety and Safeguards may not issue a license under Part 61 of this chapter, or any amendment to such a license which may significantly affect the health and safety of the public, until expressly authorized to do so by the Commission.

47 FR 57446

FINAL DECISION

§ 2.770 Final decision.

48 FR 52282

(a) The Commission will ordinarily consider the whole record on review, but may limit the issues to be reviewed and consider only findings and conclusions that were briefed after the filing of a notice of appeal.

27 FR 377

(b) The Commission may adopt, modify, or set aside the findings, conclusions and order in the initial decision, and will state the basis of its action. The final decision will be in writing and will include:

(1) A statement of findings and conclusions, with the basis for them on all material issues of fact, law or discretion presented;

(2) All facts officially noticed;

48FR52282

(3) The ruling on each material issue; and

27FR377

(4) The appropriate ruling, order, or denial of relief, with the effective date.

§ 2.771 Petition for reconsideration.

48 FR 52282

(a) A petition for reconsideration of a final decision may be filed by a party within ten (10) days after the date of the decision. No petition may be filed with respect to an initial decision which has become final through failure to file a notice of appeal.

42 FR 22148

(b) The petition for reconsideration shall state specifically the respects in which the final decision is claimed to be erroneous, the grounds of the petition, and the relief sought. Within ten (10) days after a petition for reconsideration has been filed, any other party may file an answer in opposition to or in support of the petition. However, the staff may file such an answer within twelve (12) days after a petition for reconsideration has been filed.

27 FR 377

(c) Neither the filing nor the granting of the petition shall stay the decision unless the Commission orders otherwise.

§ 2.772 Authority of the Secretary to rule on procedural matters.

39 FR 24219

When briefs, motions or other papers listed herein are submitted to the Commission itself, as opposed to officers who have been delegated authority to act for the Commission, the Secretary or the Assistant Secretary are authorized to:

(a) Prescribe schedules for the filing of briefs, motions, or other pleadings, where such schedules may differ from those elsewhere prescribed in these rules or where these rules do not prescribe a schedule;

(b) Rule on motions for extensions of time;

(c) Reject motions, briefs, pleadings, and other documents filed with the Commission later than the time prescribed by the Secretary or the Assistant Secretary or established by an order, rule, or regulation of the Commission unless good cause is shown for the late filing;

(d) Prescribe all procedural arrangements relating to any oral argument to be held before the Commission;

43 FR 22345

(e) Extend the time for the Commission to rule on a petition for review under 10 CFR 2.786(b);

(f) Extend the time for the Commission to grant review on its own motion under 10 CFR 2.786(a);

(g) Extend time for Commission review on its own motion of a Director's denial under 10 CFR 2.206(c); and

46 FR 34794

(h) Direct pleadings improperly filed before the Commission to the appropriate adjudicatory board for action.

47 FR 47802

(i) Deny a request for hearings, where the request fails to comply with the Commission's pleading requirements set forth in this Part, and fails to set forth an arguable basis for further proceedings.

(j) Refer to the Atomic Safety and Licensing Board Panel or an Administrative Law Judge, as appropriate, requests for hearings not falling under section 2.104 of this Part, where the requester is entitled to further proceedings.

(k) Take action on minor procedural matters.

EX PARTE COMMUNICATIONS

§ 2.780 Ex parte communications.

(a) Except as provided in paragraph (e) of this section, neither (1) Commissioners, members of their immediate staffs, or other NRC officials and employees who advise the Commissioners in the exercise of their quasi-judicial functions will request or entertain off the record except from each other, nor (2) any party to a proceeding for the issuance, denial, amendment, transfer, renewal, modification, suspension, or revocation of a license or permit, or any officer, employee, representative, or any other person directly or indirectly acting in behalf thereof, shall submit off the record to Commissioners or such staff members, officials, and employees, any evidence, explanation, analysis, or advice, whether written or oral, regarding any substantive matter at issue in a proceeding on the record then pending before the NRC for the issuance, denial, amendment, transfer, renewal, modification, suspension, or revocation of a license or permit. For the purposes of this section, the term "proceeding on the record then pending before the NRC" shall include any application or matter which has been noticed for hearing or concerning which a hearing has been requested pursuant to this part.

37 FR 15127

(b) Copies of written communications covered by paragraph (a) of this section shall be placed in the NRC public document room and served by the Secretary on the communicator and the parties to the proceeding involved.

(c) A Commissioner, member of his immediate staff, or other NRC official or employee advising the Commissioners in the exercise of their quasi-judicial functions, to whom is attempted any oral communication concerning any substantive matter at issue in a proceeding on the record as described in paragraph (a) of this section, will decline to listen to such communication and will explain that the matter is pending for determination. If unsuccessful in preventing such communication, the recipient thereof will advise the communicator that a written summary of the conversation will be delivered to the NRC public document room and a copy served by the Secretary of the Commission on the communicator and the parties to the proceeding involved. The recipient of the oral communication thereupon will make a fair, written summary of such communication and deliver such summary to the NRC public document room and serve copies thereof upon the communicator and the parties to the proceeding involved.

27 FR 377

(d) This section does not apply to communications authorized by paragraph (e) of this section, to the disposition of ex parte matters authorized by law, or to communications requested by the Commission concerning:

(1) Its proprietary functions;

(2) General health and safety problems and responsibilities of the Commission; or

(3) The status of proceedings.

(e) In any adjudication for the determination of an application for initial licensing, other than a contested proceeding, Commissioners, members of their immediate staffs and other NRC officials and employees who advise the Commissioners in the exercise of their quasi-judicial functions may consult the staff, and the staff may communicate with Commissioners, members of their immediate staffs and other NRC officials and employees who advise the Commissioners in the exercise of their quasi-judicial functions.

(f) The provisions and limitations of this section applicable to Commissioners, members of their immediate staffs, and other NRC officials and employees who advise the Commissioners in the exercise of their quasi-judicial functions are applicable to members of the Atomic Safety and Licensing Appeal Board, members of their immediate staffs, and other NRC officials and employees who advise members of the Appeal Board in the exercise of their quasi-judicial functions.

31 FR 12774

(g) In the case of an application for a license under Part 60 of this chapter (relating to disposal of high-level radioactive wastes in geologic repositories), this part requires a proceeding on the record prior to the issuance of a construction authorization. Unless the Commission orders otherwise, the issuance of a construction authorization (or a final decision to deny a construction authorization) shall be deemed, for purposes of this section, to terminate all proceedings on the record then pending before the NRC with respect to such application.

46 FR 13971

ATOMIC SAFETY AND LICENSING APPEAL BOARD

37 FR 22791

§ 2.785 Functions of Atomic Safety and Licensing Appeal Board.

(a) The Commission has authorized Atomic Safety and Licensing Appeal Board to exercise the authority and perform the review functions which would otherwise have been exercised and performed by the Commission, including, but not limited to, those under §§ 2.760-2.771, 2.912, and 2.913 in: (1) Proceedings on applications for licenses under Part 50 of this chapter and (2) such other licensing proceedings under the regulations in this chapter as the Commission may specify.

40 FR 8774

(next page is 2-35)

41 FR 53328

(b)(1) In the proceedings described in paragraph (a) of this section, the Atomic Safety and Licensing Appeal Board will also exercise the authority and perform the functions which would otherwise have been exercised and performed by the Commission under §§ 2.711, 2.717(a), 2.718(i), 2.720(f), 2.730, 2.742(b), 2.743(b), 2.752 (a) and (c) and Subpart I, except those functions referred to in § 2.905 (c), (e)(2), (g), and (h)(2).

42 FR 67088

(2) In a proceeding on an application for an operating license where the Atomic Safety and Licensing Appeal Board determines that a serious safety, environmental, or common defense and security matter exists that has not been raised by the parties, it may give appropriate consideration to that matter.

40 FR 8774

(c) In the proceedings described in paragraph (a) of this section, the Atomic Safety and Licensing Appeal Board shall exercise the authority and perform the functions delegated to it subject to the provisions and limitations of the referenced sections and subpart. Except as provided in § 2.786, any action taken by the Atomic Safety and Licensing Appeal Board pursuant to its delegated authority shall have the same force and effect and shall be made, evidenced, and enforced in the same manner as actions of the Commission.

(d) In the proceedings described in paragraph (a) of this section, an Atomic Safety and Licensing Appeal Board may, either in its discretion or on direction of the Commission, certify to the Commission for its determination major or novel questions of policy, law or procedure.

§ 2.786 Review of decisions and actions of an Atomic Safety and Licensing Appeal Board.

45 FR 73465

(a) Within forty (40) days after the date of a decision or action by an Atomic Safety and Licensing Appeal Board under § 2.785, or within thirty (30) days after a petition for review of such decision or action has been filed under paragraph (b) of this section, the Commission may, in cases of exceptional legal or policy importance, review the decision or action on its own motion.

42 FR 22128

(b)(1) Within fifteen (15) days after service of a decision or action by an Atomic Safety and Licensing Appeal Board under § 2.785 other than a decision or action on a referral or certification under §§ 2.718(i) or 2.730(f), a party may file a petition for review with the Commission on the ground that the decision or action is erroneous with respect to an important question of fact, law, or policy.

(2) A petition for review under this paragraph shall be no longer than ten (10) pages, and shall contain the following:

(i) A concise summary of the decision or action of which review is sought;

(ii) A statement (including record citation) where the matters of fact or law raised in the petition for review were previously raised before the Atomic Safety and Licensing Appeal Board and, if they were not why they could not have been raised;

(iii) A concise statement why in the petitioner's view the decision or action is erroneous; and

(iv) A concise statement why Commission review should be exercised.

(3) Any other party to the proceeding may, within ten (10) days after service of a petition for review, file an answer opposing Commission review. Such an answer shall be no longer than ten (10) pages and should concisely address the matters in paragraph (b)(2) of this section to the extent appropriate. No answer in support of a petition for review or further replies to answers will be entertained by the Commission.

42 FR 22128

(4) The grant or denial of a petition for review is within the discretion of the Commission, except that:

(i) A petition for review of matters of law or policy will not ordinarily be granted unless it appears the case involves an important matter that could significantly affect the environment, the public health and safety, or the common defense and security, constitutes an important antitrust question, involves an important procedural issue, or otherwise raises important questions of public policy;

(ii) A petition for review of matters of fact will not be granted unless it appears that the Atomic Safety and Licensing Appeal Board has resolved a factual issue necessary for decision in a clearly erroneous manner contrary to the resolution of that same issue by the Atomic Safety and Licensing Board;

(iii) A petition for review will not be granted to the extent that it relies on matters that could have been but were not raised before the Atomic Safety and Licensing Appeal Board. A matter raised sua sponte by an Appeal Board has been raised before the Appeal Board for the purpose of this section; and

(iv) A petition for review will not be granted as to issues raised before the Atomic Safety and Licensing Appeal Board on a pending motion for reconsideration.

45 FR 45890

(5) If within thirty (30) days after the filing of a petition for review the Commission does not grant the petition, in whole or in part, the petition shall be deemed denied, unless the Commission in its discretion extends the time for its consideration of the petition and any answers thereto.

42 FR 22128

(6) If a petition for review is granted, the Commission may issue an order specifying the issues to be reviewed and designating the parties to the review proceeding and direct that appropriate briefs be filed, oral argument be held, or both.

(7) Petitions for reconsideration of Commission decisions upon review, or granting or denying review in whole or in part, will not be entertained.

(8) Neither the filing nor the granting of a petition for review will stay the effect of the decision or action of the Atomic Safety and Licensing Appeal Board, unless otherwise ordered by the Commission.

(9) Except as provided in this section and Section 2.788, no petition or other request for Commission review of a decision or action of an Atomic Safety and Licensing Appeal Board will be entertained.

§ 2.787 Composition of Atomic Safety and Licensing Appeal Boards.

49 FR 24110

(a) An Atomic Safety and Licensing Appeal Board is composed of three members, possessing qualifications deemed appropriate to the issues to be decided, assigned for each proceeding from the Atomic Safety and Licensing Appeal Panel. Members shall be assigned by the permanent Chairman of the Panel or, in his or her absence, by the most senior available full-time member of the Appeal Panel. For purposes of this section, seniority will be determined according to the date of appointment as a member of the Atomic Safety and Licensing Appeal Panel. The Chairman of an Appeal Board for a particular proceeding shall be qualified in the conduct of administrative proceedings. An alternate may be assigned to serve as a member of an Atomic Safety and Licensing Appeal Board for a particular proceeding in the event that a member asigned to such proceeding becomes unavailable.

(b) In the absence of a quorum, the following individuals are authorized to act for an Appeal Board on procedural matters, including requests for stays of orders by presiding officers:

(1) The Chairman of the Appeal Board assigned for a particular proceeding;

(2) The permanent Chairman of the Atomic Safety and Licensing Appeal Panel, in the event that the Chairman for a particular proceeding is not available to act upon the matter in question, or has not been assigned.

(3) The most senior available full-time member of the Appeal Panel, in the event that (i) the Chairman for a particular proceeding is unavailable or has not been assigned, and (ii) the permanent Chairman of the Appeal Panel is unavailable or the position is vacant.

(c)(1) Except with respect to requests for stays of orders of presiding officers, action by a designated individual under the authority of paragraph (b) of this

section shall be reviewable by the Appeal Board for the particular proceeding, upon its own motion or upon a motion filed within three (3) days of the date of the particular action in accordance with § 2.730.

(2) Action under the authority of paragraph (b) of this section with respect to requests for stays of orders of presiding officers shall be reviewable by the Commission, upon its own motion or upon a motion filed within three (3) days of the date of the particular action in accordance with § 2.730.

§ 2.788 Stays of decisions of presiding officers and Atomic Safety and Licensing Appeal boards pending review.

(a) Within ten (10) days after service of a decision or action any party to the proceeding may file an application for a stay of the effectiveness of the decision or action pending filing of and a decision on an appeal or petition for review. Except as provided in paragraph (f) of this section, such an application may be filed with the Commission, Atomic Safety and Licensing Appeal Board, or the presiding officer.

(b) An application for a stay shall be no longer than ten (10) pages, exclusive of affidavits, and shall contain the following:

(1) A concise summary of the decision or action whch is requested to be stayed;

(2) A concise statement of the grounds for stay, with reference to the factors specified in paragraph (e) of this section;

(3) In the case of an application to the Commission for stay of decisions or actions by an Atomic Safety and Licensing Appeal Board, a statement where (including record citation, if available) a stay was requested from the Appeal Board and denied. If no such request was made of the Appeal Board, the application should state why it could not have been made; and

(4) To the extent that an application for a stay relies on facts subject to dispute, appropriate references to the record or affidavits by knowledgeable persons.

(c) Service of an application for a stay on the other parties shall be by the same method, e.g. telegram, mail, as the method for filing the application with the Commission, Atomic Safety and Licensing Appeal Board, or the presiding officer.

(d) Within ten (10) days after service of an application for a stay under this section, any party may file an answer supporting or opposing the granting of a stay. Such answer shall be no longer than ten (10) pages, exclusive of affidavits, and should concisely address the matters in paragraph (b) of this section to the extent appropriate. No further replies to answers will be entertained. Filing of and service of an answer on the other parties shall be by the same method, e.g. telegram, mail, as the method for filing the application for the stay.

(e) In determining whether to grant or deny an application for a stay, the Commission, Atomic Safety and Licensing Appeal Board, or presiding officer will consider:

(1) Whether the moving party has made a strong showing that it is likely to prevail on the merits;

(2) Whether the party will be irreparably injured unless a stay is granted;

(3) Whether the granting of a stay would harm other parties, and

(4) Where the public interest lies.

(f) An application to the Commission for a stay of a decision or action by an Atomic Safety and Licensing Appeal Board will be denied if a stay was not, but could have been, sought before the Appeal Board. An application for a stay of a decision or action of a presiding officer may be filed before either the Atomic Safety and Licensing Appeal Board or the presiding officer, but not both at the same time.

(g) In extraordinary cases, where prompt application is made under this section, the Commission, Atomic Safety and Licensing Appeal Board, or presiding officer may grant a temporary stay to preserve the status quo without waiting for filing of any answer. The application may be made orally provided the application is promptly confirmed by telegram. Any party applying under this paragraph shall make all reasonable efforts to inform the other parties of the application, orally if made orally.

(h) A party may file an application for a stay of a decision or action granting or denying a stay. As to a decision or action of a presiding officer the application shall be filed with the Atomic Safety and Licensing Appeal Board. As to a decision or action of the Atomic Safety and Licensing Appeal Board the application shall be filed with the Commission. In each case the procedures and criteria of paragraphs 2.788(a)–(e) shall be followed.

AVAILABILITY OF OFFICIAL RECORDS

§ 2.790 Public inspections, exemptions, requests for withholding.

(a) Subject to the provisions of paragraphs (b), (d), and (e) of this section, final NRC records and documents,[10] including but not limited to correspondence to and from the NRC regarding the issuance, denial, amendment, transfer, renewal, modification, suspension, revocation, or violation of a license, permit, or order, or regarding a rule making proceeding subject to this part shall not, in the absence of a compelling reason for nondisclosure after a balancing of the interests of the person or agency urging nondisclosure and the public interest in disclosure, be exempt from disclosure and will be made available for inspection and copying in the NRC Public Document Room, except for matters that are:

(1) (i) Specifically authorized under criteria established by an Executive order to be kept secret in the interest of national defense or foreign policy and (ii) are in fact properly classified pursuant to such Executive order;

(2) Related solely to the internal personnel rules and practices of the Commission;

(3) specifically exempted from disclosure by statute (other than 5 U.S.C. 552(b), provided that such statute (i) requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue, or (ii) establishes particular criteria for withholding or refers to particular types or matters to be withheld.

(4) Trade secrets and commercial or financial information obtained from a person and privileged or confidential;

(5) Interagency or intraagency memorandums or letters which would not be available by law to a party other than an agency in litigation with the Commission;

(6) Personnel and medical files and similar files, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;

(7) Investigatory records compiled for law enforcement purposes, but only to the extent that the production of such records would (i) interfere with enforcement proceedings, (ii) deprive a person of a right to a fair trial or an impartial adjudication, (iii) constitute an unwarranted invasion of personal privacy,

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[10] Such records and documents do not include handwritten notes and drafts.

(iv) disclose the identity of a confidential source and, in the case of a record compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, confidential information furnished only by the confidential source, (v) disclose investigative techniques and procedures, or (vi) endanger the life or physical safety of law enforcement personnel;

(8) Contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions; or

(9) Geological and geophysical information and data, including maps, concerning wells.

(b) (1) A person who proposes that a document or a part be withheld in whole or part from public disclosure on the ground that it contains trade secrets or privileged or confidential commercial or financial information shall submit an application for withholding accompanied by an affidavit which:

(i) Identifies the document or part sought to be withheld and the position of the person making the affidavit, and

41 FR 11808

(ii) Contains a full statement of the reasons on the basis of which it is claimed that the information should be withheld from public disclosure. Such statement shall address with specificity the considerations listed in paragraph (b) (4) of this section.

In the case of an affidavit submitted by a company, the affidavit shall be executed by an officer or upper-level management official who has been specifically delegated the function of reviewing the information sought to be withheld and authorized to apply for its withholding on behalf of the company. The affidavit shall be executed by the owner of the information, even though the information sought to be withheld is submitted to the Commission by another person. The application and affidavit shall be submitted at the time of filing the information sought to be withheld. The information sought to be withheld shall be incorporated, as far as possible, into a separate paper.

The affiant may designate with appropriate markings information submitted in the affidavit as a trade secret or confidential or privileged commercial or financial information within the meaning of § 9.5(a)(4) of this chapter and such information shall be subject to disclosure only in accordance with the provisions of § 9.12 of this chapter.

(2) A person who submits commercial or financial information believed to be privileged or confidential or a trade secret shall be on notice that it is the policy of the Commission to achieve an effective balance between legitimate concerns for protection of competitive positions and the right of the public to be fully apprised as to the bases for and effects of licensing or rule making actions, and that it is within the discretion of the Commission to withhold such information from public disclosure.

(3) The Commission shall determine whether the information sought to be withheld from public disclosure pursuant to this paragraph: (i) is a trade secret or confidential or privileged commercial or financial information; and (ii) if so, should be withheld from public disclosure.

(4) In making the determination required by paragraph (b)(3)(i) of this section, the Commission will consider:

(i) Whether the information has been held in confidence by its owner;

41 FR 11808

(ii) Whether the information is of a type customarily held in confidence by its owner and whether there is a rational basis therefor;

(iii) Whether the information was transmitted to and received by the Commission in confidence;

(iv) Whether the information is available in public sources;

(v) Whether public disclosure of the information sought to be withheld is likely to cause substantial harm to the competitive position of the owner of the information, taking into account the value of the information to the owner; the amount of effort or money, if any, expended by the owner in developing the information; and the ease or difficulty with which the information could be properly acquired or duplicated by others.

(5) If the Commission determines, pursuant to paragraph (b)(4) of this section, that the record or document contains trade secrets or privileged or confidential commercial or financial information, the Commission will then determine (i) whether the right of the public to be fully apprised as to the bases for and effects of the proposed action outweighs the demonstrated concern for protection of a competitive position and (ii) whether the information should be withheld from public disclosure pursuant to this paragraph. If the record or document for which withholding is sought is deemed by the Commission to be irrelevant or unnecessary to the performance of its functions, it shall be returned to the applicant.

(6) Withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned to inspect the document. The Commission may require information claimed to be a trade secret or privileged or confidential commercial or financial information to be subject to inspection: (i) under a protective agreement, by contractor personnel or government officials other than NRC officials; (ii) by the presiding officer in a proceeding; and (iii) under protective order, by parties to a proceeding, pending a decision of the Commission on the matter of whether the information should be made publicly available or when a decision has been made that the information should be withheld from public disclosure. In camera sessions of hearings may be held when the information sought to be withheld is produced or offered in evidence. If the Commission subsequently determines that the information should be disclosed, the information and the transcript of such in camera session will be made publicly available.

41 FR 11808

(c) If a request for withholding pursuant to paragraph (b) of this section is denied, the Commission will notify an applicant for withholding of the denial with a statement of reasons. The notice or denial will specify a time, not less than thirty (30) days after the date of the notice, when the document will be placed in the Public Document Room. If, within the time specified in the notice, the applicant requests withdrawal of the document, the document will not be placed in the Public Document Room and will be returned to the applicant: Provided, That information submitted in a rule making proceeding which subsequently forms the basis for the final rule will not be withheld from public disclosure by the Commission and will not be returned to the applicant after denial of any application for withholding submitted in connection with that information. If a request for withholding pursuant to paragraph (b) of this section is granted, the Commission will notify the applicant of its determination to withhold the information from public disclosure.

(d) The following information shall be deemed to be commercial or financial information within the meaning of § 9.5(a)(4) of this chapter and shall be subject to disclosure only in accordance with the provisions of § 9.12 of this chapter: 41 FR 11808

(1) Correspondence and reports to or from the NRC which contain information or records concerning a licensee's or applicant's physical protection or material control and accounting program for special nuclear material not otherwise designated as Safeguards Information or classified as National Security Information or Restricted Data. 46 FR 51718

(2) Information submitted in confidence to the Commission by a foreign source.

(e) The presiding officer, if any, or the Commission may, with reference to the NRC records and documents made available pursuant to this section, issue orders consistent with the provisions of this section and § 2.740(c). 41 FR 11808

Subpart H—Rule Making

§ 2.800 Scope of rule making.

This subpart governs the issuance, amendment and repeal of regulations in which participation by interested persons is prescribed under section 553 of title 5 of the United States Code. 35 FR 11459

§ 2.801 Initiation of rule making.

Rule making may be initiated by the Commission at its own instance, on the recommendation of another agency of the United States, or on the petition of any other interested person. 27 FR 377

§ 2.802 Petition for rule making.

(a) Any interested person may petition the Commission to issue, amend or rescind any regulation. The petition should be addressed to the Secretary, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Chief, Docketing and Service Branch.

(b) A prospective petitioner is encouraged to confer with the staff prior to the filing of a petition for rulemaking. Questions regarding applicable NRC regulations sought to be amended, the procedures for filing a petition for rulemaking, or requests for a meeting with the appropriate NRC staff to discuss a petition should be addressed to the Director, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Chief, Rules and Procedures Branch. A prospective petitioner may also telephone the Division of Rules and Records on (301) 492-7088 to obtain assistance.

(c) Each petition filed under this section shall:

(1) Set forth a general solution to the problem or the substance or text of any proposed regulation or amendment, or specify the regulation which is to be revoked or amended;

(2) State clearly and concisely the petitioner's grounds for and interest in the action requested;

(3) Include a statement in support of the petition which shall set forth the specific issues involved, the petitioner's views or arguments with respect to those issues, relevant technical, scientific or other data involved which is reasonably available to the petitioner, and such other pertinent information as the petitioner deems necessary to support the action sought. In support of its petition, petitioner should note any specific cases of which petitioner is aware where the current rule is unduly burdensome, deficient, or needs to be strengthened.

(d) The petitioner may request the Commission to suspend all or any part of any licensing proceeding to which the petitioner is a party pending disposition of the petition for rule making. 44 FR 61320

(e) If it is determined that the petition includes the information required by paragraph (c) of this section and is complete, the Director, Division of Rules and Records, or designee, will assign a docket number to the petition, will cause the petition to be formally docketed, and will deposit a copy of the docketed petition in the Commission's Public Document Room. Public comment may be requested by publication of a notice of the docketing of the petition in the Federal Register, or, in appropriate cases, may be invited for the first time upon publication in the Federal Register of a proposed rule developed in response to the petition. Publication will be limited by the requirements of section 181 of the Atomic Energy Act of 1954, as amended, and may be limited by order of the Commission. 46 FR 35486

(f) If it is determined by the Executive Director for Operations that the petition does not include the information required by paragraph (c) of this section and is incomplete, the petitioner will be notified of that determination and the respects in which the petition is deficient and will be accorded an opportunity to submit additional data. Ordinarily this determination will be made within 30 days from the date of receipt of the petition by the Office of the Secretary of the Commission. If the petitioner does not submit additional data to correct the deficiency within 90 days from the date of notification to the petitioner that the petition is incomplete, the petition may be returned to the petitioner without prejudice to the right of the petitioner to file a new petition.

(g) The Director, Division of Rules and Records, Office of Administration, or his designee, will prepare on a quarterly basis a summary of petitions for rule making pending before the Commission, including the status thereof. A copy of the report will be available for public inspection and copying in the Commission's Public Document Room, 1717 H Street, N.W., Washington, D.C. 20555. 44 FR 61320

§ 2.803 Determination of petition.

No hearing will be held on the petition unless the Commission deems it advisable. If the Commission determines that sufficient reason exists, it will publish a notice of proposed rule making. In any other case, it will deny the petition and will notify the petitioner with a simple statement of the grounds of denial. 27 FR 377

§ 2.804 Notice of proposed rule making.

(a) Except as provided by paragraph (d) of this section, when the Commission proposes to adopt, amend, or repeal a regulation, it will cause to be published in the **Federal Register** a notice of proposed rulemaking, unless all persons subject to the notice are named and either are personally served or otherwise have actual notice in accordance with law. 50 FR 13006

(b) The notice will include:

(1) Either the terms or substance of the proposed rule, or a specification of the subjects and issues involved;

(2) The manner and time within which interested members of the public may comment, and a statement that copies of comments may be examined in the Public Document Room; 27 FR 377

(3) The authority under which the regulation is proposed;

(4) The time, place, and nature of the public hearing, if any;

(5) If a hearing is to be held, designation of the presiding officer and any special directions for the conduct of the hearing; and

(6) Such explanatory statement as the Commission may consider appropriate.

(c) The publication or service of notice will be made not less than fifteen (15) days prior to the time fixed for hearing, if any, unless the Commission for good cause stated in the notice provides otherwise.

27 FR 377

(d) The notice and comment provisions contained in paragraphs (a), (b), and (c) of this section will not be required to be applied—

(1) To interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or

(2) When the Commission for good cause finds that notice and public comment are impracticable, unnecessary, or contrary to the public interest, and are not required by statute. This finding, and the reasons therefor, will be incorporated into any rule issued without notice and comment for good cause.

(e) The Commission shall provide for a 30-day post-promulgation comment period for—

(1) Any rule adopted without notice and comment under the good cause exception on paragraph (d)(2) of this section where the basis is that notice and comment is "impracticable" or "contrary to the public interest."

(2) Any interpretative rule, or general statement of policy adopted without notice and comment under paragraph (d)(1) of this section, except for those cases for which the Commission finds that such procedures would serve no public interest, or would be so burdensome as to outweigh any foreseeable gain.

(f) For any post-promulgation comments received under paragraph (e) of this section, the Commission shall publish a statement in the **Federal Register** containing an evaluation of the significant comments and any revisions of the rule or policy statement made as a result of the comments and their evaluation.

§ 2.805 Participation by interested persons.

(a) In all rulemaking proceedings conducted under the provisions of § 2.804(a), the Commission will afford interested persons an opportunity to participate through the submission of statements, information, opinions, and arguments in the manner stated in the notice. The Commission may grant additional reasonable opportunity for the submission of comments.

50 FR 13006

(b) The Commission may hold informal hearings at which interested persons may be heard, adopting procedures which in its judgment will best serve the purpose of the hearing.

§ 2.806 Commission action.

The Commission will incorporate in the notice of adoption of a regulation a concise general statement of its basis and purpose, and will cause the notice and regulation to be published in the FEDERAL REGISTER or served upon affected persons.

§ 2.807 Effective date.

The notice of adoption of a regulation will specify the effective date. Publication or service of the notice and regulation, other than one granting or recognizing exemptions or relieving from restrictions, will be made not less than thirty (30) days prior to the effective date unless the Commission directs otherwise on good cause found and published in the notice of rule making.

27 FR 377

§ 2.808 Authority of the Secretary to Rule on Procedural Matters.

When briefs, motions or other papers listed herein are submitted to the Commission itself, as opposed to officers who have been delegated authority to act for the Commission, the Secretary or the Assistant Secretary are authorized to:

(a) Prescribe schedules for the filing of statements, information, briefs, motions, responses or other pleadings, where such schedules may differ from those elsewhere prescribed in these rules or where these rules do not prescribe a schedule.

(b) Rule on motions for extensions of time;

(c) Reject motions, briefs, pleadings, and other documents filed with the Commission later than the time prescribed by the Secretary or the Assistant Secretary or established by an order, rule, or regulation of the Commission unless good cause is shown for the late filing; and

(d) Prescribe all procedural arrangements relating to any oral argument to be held before the Commission.

39 FR 24219

§ 2.809 Participation by the Advisory Committee on Reactor Safeguards.

(a) In its advisory capacity to the Commission, the ACRS may recommend that the Commission initiate rulemaking in a particular area. The Commission will respond to such rulemaking recommendation in writing within 90 days, noting its intent to implement, study, or defer action on the recommendation. In the event the Commission decides not to accept or decides to defer action on the recommendation, it will give its reasons for doing so. Both the ACRS recommendation and the Commission's response will be placed in the NRC Public Document Room following transmittal of the Commission's response to the ACRS.

(b) When a rule involving nuclear safety matters within the purview of the ACRS is under development by the NRC Staff, the Staff will ensure that the ACRS is given an opportunity to provide advice at appropriate stages and to identify issues to be considered during rulemaking hearings.

46 FR 22358

Subpart I—Special Procedures Applicable to Adjudicatory Proceedings Involving Restricted Data and/or National Security Information

§ 2.900 Purpose.

This subpart is issued pursuant to section 181 of the Atomic Energy Act of 1954, as amended, and section 201 of the Energy Reorganization Act of 1974, as amended, to provide such procedures in proceedings subject to this part as will effectively safeguard and prevent disclosure of Restricted Data and National Security Information to unauthorized persons, with minimum impairment of procedural rights.

§ 2.901 Scope.

This subpart applies to all proceedings subject to subpart G.

§ 2.902 Definitions.

As used in this subpart:

(a) "Government agency" means any executive department, commission, independent establishment, corporation, wholly or partly owned by the United States of America, which is an instrumentality of the United States, or any board, bureau, division, service, office, officer, authority, administration, or other establishment in the executive branch of the Government.

(b) "Interested party" means a party having an interest in the issue or issues to which particular Restricted Data or National Security Information is relevant. Normally the interest of a party in an issue may be determined by examination of the notice of hearing, the answers and replies.

41 FR 53328

41FR53328

(c) The phrase "introduced into a proceeding" refers to the introduction or incorporation of testimony or documentary matter into any part of the official record of a proceeding subject to this part.

47 FR 56314

(d) "National Security Information" means information that has been classified pursuant to Executive Order 12356.

41 FR 53328

(e) "Party," in the case of proceedings subject to this subpart includes a person admitted as a party pursuant to § 2.714 or in interested State admitted pursuant to § 2.715(e).

§ 2.903 Protection of restricted data and national security information.

Nothing in this subpart shall relieve any person from safeguarding Restricted Data or National Security Information in accordance with the applicable provisions of laws of the United States and rules, regulations or orders of any Government Agency.

§ 2.904 Classification assistance.

On request of any party to a proceeding or of the presiding officer, the Commission will designate a representative to advise and assist the presiding officer and the parties with respect to security classification of information and the safeguards to be observed.

§ 2.905 Access to restricted data and national security information for parties; security clearances.

(a) Access to restricted data and national security information introduced into proceedings. Except as provided in paragraph (h) of this section, restricted data or national security information introduced into a proceeding subject to this part will be made available to any interested party having the required security clearance; to counsel for an interested party provided the counsel has the required security clearance; and to such additional persons having the required security clearance as the Commission or the presiding officer determined are needed by such party for adequate preparation or presentation of his case. Where the interest of such party will not be prejudiced, the Commission or presiding officer may postpone action upon an application for access under this subparagraph until after a notice of hearing, answers, and replies have been filed.

41 FR 53328

(b) Access to Restricted Data or National Security Information not introduced into proceedings. (1) On application showing that access to Restricted Data or National Security Information may be required for the preparation of a party's case, and except as provided in paragraph (h) of this section, the Commission or the presiding officer will issue an order granting access to such Restricted Data or National Security Information to the party upon his obtaining the required security clearance, to counsel for the party upon their obtaining the required security clearance, and to such other individuals as may be needed by the party for the preparation and presentation of his case upon their obtaining the required clearance.

(2) Where the interest of the party applying for access will not be prejudiced, the Commission or the presiding officer may postpone action on an application pursuant to this paragraph until after a notice of hearing, answers and replies have been filed.

(c) The Commission will consider requests for appropriate security clearances in reasonable numbers pursuant to this section. A reasonable charge will be made by the Commission for costs of security clearance pursuant to this section.

(d) The presiding officer may certify to the Commission for its consideration and determination any questions relating to access to Restricted Data or National Security Information arising under this section. Any party affected by a determination or order of the presiding officer under this section may appeal forthwith to the Commission from the determination or order. The filing by the staff of an appeal from an order of a presiding officer granting access to Restricted Data or National Security Information shall stay the order pending determination of the appeal by the Commission.

(e) Application granting access to restricted data or national security information. (1) An application under this section for orders granting access to restricted data or national security information not received from another Government agency will normally be acted upon by the presiding officer, or if a proceeding is not before a presiding officer, by the Commission. (2) An application under this section for orders granting access to restricted data or national security information where the information has been received by the Commission from another Government agency will be acted upon by the Commission.

41 FR 53328

(f) To the extent practicable, an application for an order granting access under this section shall describe the subjects of Restricted Data or National Security Information to which access is desired and the level of classification (confidential, secret or other) of the information; the reasons why access to the information is requested; the names of individuals for whom clearances are requested; and the reasons why security clearances are being requested for those individuals.

(g) On the conclusion of a proceeding, the Commission will terminate all orders issued in the proceeding for access to Restricted Data or National Security Information and all security clearances granted pursuant to them; and may issue such orders requiring the disposal of classified matter received pursuant to them or requiring the observance of other procedures to safeguard such classified matter as it deems necessary to protect Restricted Data or National Security information.

(h) Refusal to grant access to restricted data or national security information. (1) The Commission will not grant access to restricted data or national security information unless it determines that the granting of access will not be inimical to the common defense and security. (2) Access to Restricted Data or National Security Information which has been received by the Commission from another Government agency will not be granted by the Commission if the originating agency determines in writing that access should not be granted. The Commission will consult the originating agency prior to granting access to such data or information received from another Government agency.

§ 2.906 Obligation of parties to avoid introduction of restricted data or national security information.

It is the obligation of all parties in a proceeding subject to this part to avoid, where practicable, the introduction of Restricted Data or National Security Information into the proceeding. This obligation rests on each party whether or not all other parties have the required security clearance.

§ 2.907 Notice of intent to introduce restricted data or national security information.

41 FR 53328

(a) If, at the time of publication of a notice of hearing, it appears to the staff that it will be impracticable for it to avoid the introduction of Restricted Data or National Security Information into the proceeding, it will file a notice of intent to introduce Restricted Data or National Security Information.

(b) If, at the time of filing of an answer to the notice of hearing it appears to the party filing that it will be impracticable for the party to avoid the introduction of Restricted Data or National Security Information into the proceeding, the party shall state in the answer a notice of intent to introduce Restricted Data or National Security Information into the proceeding.

(c) If, at any later stage of a proceeding, it appears to any party that it will be impracticable to avoid the introduction of Restricted Data or National Security Information into the proceeding, the party shall give to the other parties prompt written notice of intent to introduce Restricted Data or National Security Information into the proceeding.

(d) Restricted Data or National Security Information shall not be introduced into a proceeding after publication of a notice of hearing unless a notice of intent has been filed in accordance with § 2.908, except as permitted in the discretion of the presiding officer when it is clear that no party or the public interest will be prejudiced.

§ 2.908 Contents of notice of intent to introduce restricted data or other national security information.

(a) A party who intends to introduce Restricted Data or other National Security Information shall file a notice of intent with the Secretary. The notice shall be unclassified and, to the extent consistent with classification requirements, shall include the following:

(1) The subject matter of the Restricted Data or other National Security Information which it is anticipated will be involved;

(2) The highest level of classification of the information (confidential, secret, or other);

(3) The stage of the proceeding at which he anticipates a need to introduce the information; and

(4) The relevance and materiality of the information to the issues on the proceeding.

(b) In the discretion of the presiding officer, such notice, when required by § 2.907(c), may be given orally on the record.

41 FR 53328

§ 2.909 Rearrangement or suspension of proceedings.

In any proceeding subject to this part where a party gives a notice of intent to introduce Restricted Data or other National Security Information, and the presiding officer determines that any other interested party does not have required security clearances, the presiding officer may in his discretion:

(a) Rearrange the normal order of the proceeding in a manner which gives such interested parties an opportunity to obtain required security clearances with minimum delay in the conduct of the proceeding.

(b) Suspend the proceeding or any portion of it until all interested parties have had opportunity to obtain required security clearances. No proceeding shall be suspended for such reasons for more than 100 days except with the consent of all parties or on a determination by the presiding officer that further suspension of the proceeding would not be contrary to the public interest.

(c) Take such other action as he determines to be in the best interest of all parties and the public.

§ 2.910 Unclassified statements required.

(a) Whenever Restricted Data or other National Security Information is introduced into a proceeding, the party offering it shall submit to the presiding officer and to all parties to the proceeding an unclassified statement setting forth the information in the classified matter as accurately and completely as possible.

(b) In accordance with such procedures as may be agreed upon by the parties or prescribed by the presiding officer, and after notice to all parties and opportunity to be heard thereon, the presiding officer shall determine whether the unclassified statement or any portion of it, together with any appropriate modifications suggested by any party, may be substituted for the classified matter or any portion of it without prejudice to the interest of any party or to the public interest.

(c) If the presiding officer determines that the unclassified statement, together with such unclassified modifications as he finds are necessary or appropriate to protect the interest of other parties and the public interest, adequately sets forth information in the classified matter which is relevant and material to the issues in the proceeding, he shall direct that the classified matter be excluded from the record of the proceeding. His determination will be considered by the Commission as a part of the decision in the event of review.

41 FR 53328

(d) If the presiding officer determines that an unclassified statement does not adequately present the information contained in the classified matter which is relevant and material to the issues in the proceeding, he shall include his reasons in his determination. This determination shall be included as part of the record and will be considered by the Commission in the event of review of the determination.

(e) The presiding officer may postpone all or part of the procedures established in this section until the reception of all other evidence has been completed. Service of the unclassified statement required in paragraph (a) of this section shall not be postponed if any party does not have access to Restricted Data or other National Security Information.

§ 2.911 Admissibility of restricted data or other national security information.

A presiding officer shall not receive any Restricted Data or other National Security Information in evidence unless:

(a) The relevance and materiality of the Restricted Data or other National Security Information to the issues in the preceeding, and its competence, are clearly established; and

(b) The exclusion of the Restricted Data or other National Security Information would prejudice the interests of a party or the public interest.

§ 2.912 Weight to be attached to classified evidence.

In considering the weight and effect of any Restricted Data or other National Security Information received in evidence to which an interested party has not had opportunity to receive access, the presiding officer and the Commission shall give to such evidence such weight as is appropriate under the circumstances, taking into consideration any lack of opportunity to rebut or impeach the evidence.

41 FR 53328

§ 2.913 Review of Restricted data or other National Security Information received in evidence.

At the close of the reception of evidence, the presiding officer shall review the record and shall direct that any Restricted Data or other National Security Information be expunged from the record where such expunction would not prejudice the interests of a party or the public interest. Such directions by the presiding officer will be considered by the Commission in the event of review of the determinations of the presiding officer.

§ 2.914 [Deleted 40 FR 44124.]

APPENDIX A–STATEMENT OF GENERAL POLICY AND PROCEDURE: CONDUCT OF PROCEEDINGS FOR THE ISSUANCE OF CONSTRUCTION PERMITS AND OPERATING LICENSES FOR PRODUCTION AND UTILIZATION FACILITIES FOR WHICH A HEARING IS REQUIRED UNDER SECTION 189A OF THE ATOMIC ENERGY ACT OF 1954, AS AMENDED*

The following statement of general policy and procedure explains in detail the procedures which the Atomic Energy Commission expects to be followed by atomic safety and licensing boards in the conduct of proceedings relating to the issuance of construction permits for nuclear power and test reactors and other production or utilization facilities for which a hearing is mandatory under section 189a. of the Atomic Energy Act of 1954, as amended (the Act).[1] The provisions are also applicable to proceedings for the issuance of operating licenses for such facilities, except as the context would otherwise indicate, or except as indicated in section VIII. Section VIII sets out the procedures specifically applicable to operating license proceedings. The Statement reflects the Commission's intent that such proceedings be conducted expeditiously and its concern that its procedures maintain sufficient flexibility to accommodate that objective. This position is founded upon the recognition that fairness to all the parties in such cases and the obligation of administrative agencies to conduct their functions with efficiency and economy, require that Commission adjudications be conducted without unnecessary delays. These factors take on added importance in nuclear power reactor licensing proceedings where the growing national need for electric power and the companion need for protecting the quality of the environment call for decision making which is both sound and timely. The Commission expects that its responsibilities under the Atomic Energy Act of 1954, the National Environmental Policy Act of 1969 and other applicable statutes, as set out in the statement which follows, will be carried out in a manner consistent with this position in the overall public interest.

37 FR 15127

Atomic safety and licensing boards are appointed from time to time by the Commission or the Chairman of the Atomic Safety and Licensing Board Panel to conduct hearings in licensing cases under the authority of section 191 of the Act. Section 191 authorizes the Commission to establish one or more atomic safety and licensing boards to conduct public hearings and to make intermediate or final decisions in administrative proceedings relating to granting, suspending, revoking or amending licenses issued by the Commission. It requires that each board consist of one member who is qualified in the conduct of administrative proceedings and two members who have such technical or other qualifications as the Commission deems appropriate to the issues to be decided. Members of each board may be appointed by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel from a panel selected from private life, the staff of the Commission or other Federal agencies.

37 FR 15127

An Atomic Safety and Licensing Board may at its discretion appoint special assistants to the Board from the membership of the Atomic Safety and Licensing Board Panel established by the Commission. These special assistants are to be employed to facilitate the hearing process and improve the quality of the record produced for review. The special assistants may serve as technical interrogators in their individual fields of expertise, alternate Atomic Safety and Licensing Board members to sit with the Board and participate in the evidentiary sessions on the issue for which the alternate members were designated, Special Masters to hear evidentiary presentations by the parties on specific technical matters upon the consent of all parties, or informal consultants to brief the board prior to the hearing on the general technical background of subjects involving complex issues. The term "alternate board member" as a "special assistant" within the meaning of 10 CFR 2.722(a)(3) should not be confused with the use of the term "alternate" in 10 CFR 2.721(b). In the latter situation the "alternate" is a substitute for a member of a Board who becomes unavailable. As a special assistant, the "alternate" sits with the three-member Board and not instead of the Board or any of its members.

45 FR 62027

I. PRELIMINARY MATTERS

(a) A public hearing is announced by the issuance of a notice of hearing, published in the **Federal Register** as soon as practicable after the application has been docketed, signed by the Secretary of the Commission stating the nature of the hearing and the issues to be considered. The time and place of the first prehearing conference pursuant to § 2.751a will ordinarily be stated in the notice of hearing. Unless the initial notice of hearing states the time and place of the hearing, and the Chairman and other members of the Atomic Safety and Licensing Board that will conduct the hearing, those matters will be the subject of further notice in the **Federal Register** after publication of the initial notice of hearing. It is the Commission's policy and practice to begin the evidentiary hearing in the vicinity of the site of the proposed facility. The notice of hearing also states the procedures whereby persons may seek to intervene or make a limited appearance and explains the differences between those forms of participation in the proceeding, and states the times and places of the availability, in an appropriate office near the site of the proposed facility, of the notice of hearing, an updated copy of the application, the report of the Advisory Committee on Reactor Safeguards (ACRS), the staff safety evaluation, the applicant's environmental report, the Commission's environmental impact statement, the proposed construction permit or operating license and the transcripts of the prehearing conference and the hearing.

49 FR 9352

(b) In fixing the time and place of any conference, including prehearing conferences, or of any adjourned session of the evidentiary hearing, due regard shall be had for the convenience and necessity of the parties, petitioners for leave to intervene, or the representatives of such persons, as well as of the Board members, the nature of such conference or adjourned session, and the public interest. Adjourned sessions of hearings may be held in the Washington, D.C. area if all parties so stipulate. If the parties disagree, and any party considers that there are valid reasons for holding such session in the Washington, D.C. area, the matter should be referred to the Atomic Safety and Licensing Appeal Board for resolution.

37 FR 15127

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*In the event of any conflict between the provisions of this appendix and any section of this part, the section governs.

[1] Except as the context may otherwise indicate, this statement is also generally applicable to licensing proceedings of the type described in the statement which may be conducted by a hearing examiner as the presiding officer.

(c) (1) The Commission or the Atomic Safety and Licensing Board may consider on their own initiative, or a party may request the Commission or the board to consider, a particular issue or issues separately from, and prior to, other issues relating to the effect of the construction and/or operation of the facility upon the public health and safety, the common defense and security, and the environment or in regard to anti-trust considerations. If the Commission or the board determines that a separate hearing should be held, the notice of hearing or other appropriate notice will state the time and place of the separate hearing on such issue or issues. the board designated to conduct the hearing will issue an initial decision, if deemed appropriate, which will be dispositive of the issue(s) considered at the hearing, in the absence of an appeal or Commission or Appeal Board review pursuant to §§ 2.760 and 2.762, before the hearing on, and consideration of, the remaining issues in the proceeding.

42 FR 22882

(2) In a proceeding relating to the issuance of a construction permit for a facility which is subject to the environmental impact statement requirements of section 102(2)(C) of the National Environmental Policy Act of 1969 and subpart A of Part 51 of this chapter and which is a utilization facility for industrial or commercial purposes or is a testing facility, separate hearings may be held and decisions may be issued on National Environmental Policy Act and site suitability issues and other specified issues as provided by subpart F and § 2.761a.

(d) Prior to a hearing, board members should review and become familiar with: The record of any relevant prior proceedings in the case, including initial decisions and Commission orders, the application, the ARCS report, the staff safety evaluation, the applicant's environmental report, the Commission's environmental impact statement, all other papers filed in the proceeding, the Commission's rules of practice, and other regulations or published statements of policy of the Commission as may be pertinent to the proceeding.

49 FR 9352

(e) At any time when a board is in existence but is not actually in session, the chairman has all the powers of the board to take action on procedural matters. The chairman may have occasion, when the board is not in session, to dispose of preliminary procedural requests including, among other things, motions by parties relating to the conduct of the hearing. He may wish to discuss such requests with the other members of the board before ruling on them. No interlocutory appeal[2] may be taken by a party as a matter of right from a ruling of the chairman or the board. The board should refer the challenged ruling to the Commission for a final decision if, in its judgment, a prompt decision is necessary to prevent detriment to the public interest or unusual delay or expense. This authority should be exercised sparingly, and only when deemed essential in fairness to the parties or the public.

37 FR 15127

II. PREHEARING CONFERENCES

(a) A special prehearing conference will be held, within ninety (90) days after the notice of hearing has been published, or such other time as the Commission or the Board may deem appropriate, in addition to the standard prehearing conference provided by § 2.752. The special prehearing conference, authorized by § 2.751a, should be used to permit identification of key issues; take steps necessary for further identification of the issues; consider all intervention petitions to allow preliminary or final determination as to the parties; and establish a schedule for further actions in the proceeding.

43 FR 17798

(b) Within sixty (60) days after discovery has been completed,[3] or such other time as the presiding officer or the Commission deems appropriate, a second prehearing conference—the prehearing conference provided by § 2.752—is held to consider simplification, clarification, and specification of the issues; consider amendments to the pleadings; obtain stipulations and admissions of facts and of the contents and authenticity of documents to avoid unnecessary proof; identification of witnesses; the setting of a hearing schedule; and such other matters as may aid in the orderly disposition of the hearing.

(c) A transcript of each prehearing conference will be prepared. The board will issue an order after the conclusion of the special prehearing conference which recites the action taken at the conference and agreements by the parties, identifies the key issues in controversy, makes a preliminary or final determination as to the parties, and provides for submission of status reports on discovery by the parties. The board will also issue an order after the conclusion of the second prehearing conference that specifies the issues in controversy in the proceeding. Each order shall be served upon all parties to the proceeding. Objections to such order may be filed by a party within five (5) days, or, in the case of the staff, within ten (10) days. The board may revise the order in the light of the objections presented and, as permitted by § 2.718(i), may certify for determination to the Commission or the Appeal Board, as appropriate, such matters raised in the objections as it deems appropriate. As specified in § 2.752, the order shall control the subsequent course of the proceeding unless modified for good cause.

(d) Prehearing conferences are open to the public except under exceptional circumstances involving such matters as classified information and certain privileged information not normally a part of the hearing record.

(e) The applicant, the staff and other parties are required to provide each other and the board with copies of prepared testimony in advance of its being offered at the hearing. A schedule may be established at the second prehearing conference for exchange of prepared testimony. Prepared testimony is filed in the Commission's public document room and is available for public inspection. When the staff has reached its conclusions with respect to the application and prepared a safety evaluation, the safety evaluation will be made available—a point of time which may or may not be prior to the hearing.

37 FR 15127

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[2] An interlocutory appeal means an appeal to the Commission from a ruling made by the board during the time between the issuance of a notice of hearing and the issuance of the initial decision.

[3] "Discovery", for this purpose, does not include production of the ACRS report, the staff's safety evaluation, or the detailed statement on environmental considerations prepared by the Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate, or his designee.

III. INTERVENTION AND LIMITED APPEARANCES

(a)(1) As required by § 2.714, a person who wishes to intervene must set forth, in a petition for leave to intervene, his interest in the proceeding and how the interest may be affected by Commission action. Petitions for leave to intervene shall, as a basis for enabling the board or the Commission to determine how the petitioner's interest may be affected by the proceeding, set forth (i) the nature of his right under the Act to be made a party to the proceeding, (ii) the nature and extent of the interest that may be affected by the proceeding, and (iii) the effect of any order which may be entered in the proceeding on the petitioner's interest. The petition must identify the specific aspects as to which the petitioner wishes to intervene and set forth with particularity the facts pertaining to his interest. The petitioner must file a supplement to his petition containing his contention(s) and basis therefor not later than fifteen (15) days prior to the holding of the special prehearing conference pursuant to § 2.751a. After consideration of any answers to the petition, the board will rule on the petition. If the board finds that the petitioner's interest is limited to one or more of the issues in the proceeding, the intervenor's participation will be limited to those issues.

43 FR 17798

Petitions and supplements thereto which set forth contentions relating only to matters outside the jurisdiction of the Commission will be denied. In any event, the granting of a petition for leave to intervene does not operate to enlarge the issues, or become a basis for receipt of evidence, with respect to matters beyond the jurisdiction of the Commission.

(2) Petitions for leave to intervene which are not filed within the time specified in the notice of hearing will not be granted unless the board determines that the petition should be granted based upon paragraph (a)(1) of this section and upon a balancing of (i) good cause, if any, for petitioner's failure to file on time, (ii) the availability of other means whereby the petitioner's interest will be protected, (iii) the extent to which petitioner's participation may reasonably be expected to assist in developing a sound record, (iv) the extent to which petitioner's interest will be represented by existing parties, and (v) the extent which the petitioner's participation will broaden the issues or delay the proceedings.

(3) Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have all the rights of the applicant to participate fully in the conduct of the hearing, such as the examination and cross-examination of witnesses, with respect to their contentions related to the matters at issue in the proceeding.

(4) If more than one person who has been granted leave to intervene has substantially the same kind of interest that may be affected by the proceeding, and raises the same basic questions, the board or the Commission may order those persons to consolidate their presentation of evidence, cross-examination, briefs, proposed findings of fact and conclusions of law and argument, unless such consolidation cannot be accomplished without prejudice to the rights of a party.

(b) A person who does not wish to, or is not qualified to become a party may be permitted at the discretion of the board, to make a limited appearance pursuant to § 2.715. Persons permitted to make limited appearances do not become parties, but should be permitted to make statements at such stage of the proceeding as the board may consider appropriate. A person making a limited appearance may only make an oral or written statement on the record, and may not participate in the proceeding in any other way. The board may wish to limit the length of oral statements. A member of the public does not have the right to participate unless he has been granted the right to intervene as a party or the right of limited appearance for the purpose of making a statement.

37 FR 15127

IV. DISCOVERY

(a) Once the key issues in controversy are identified in the special prehearing conference order (§ 2.751a.(d)), discovery may proceed and will be limited to those matters. In no event should the parties be permitted to use discovery procedures to conduct a "fishing expedition" or to delay the proceeding.

(b) Under the Commission's rules of practice, discovery permitted by §§ 2.720, 2.740, 2.740a, 2.740b, 2.741, 2.742, and 2.744 must be completed by the second prehearing conference, except upon leave for good cause shown.

(c) Depositions, interrogatories and document production between parties other than the staff are obtainable on notice or request to the other party and without leave of the Commission or the board, in line with the Federal rules of Civil Procedure.

(d) In general, staff documents that are relevant to a proceeding will be publicly available as a matter of course unless there is a compelling justification for their nondisclosure. Therefore, document discovery directed at the staff will be restricted, as provided in § 2.744, since most staff documents will be publicly available and should reasonably disclose the basis for the staff's position. Formal discovery of documents against the staff will be limited to cases where it concerns a matter necessary to a proper decision in a case and the information sought is not obtainable elsewhere. Discovery as a legitimate means of obtaining information will not be inhibited, but in view of the comprehensive body of information routinely available without request, there should be minimum need to resort to time consuming discovery procedures. Discovery against the staff (and other NRC personnel, including consultants) by way of deposition is permitted upon a showing of exceptional circumstances. Interrogatories may be addressed to the staff where the information is necessary to proper decision in the case and not obtainable elsewhere.

V. THE HEARING

The board should use its powers under §§ 2.718 and 2.757 to assure that the hearing is focused upon the matters in controversy among the parties and that the hearing process for the resolution of controverted matters is conducted as expeditiously as possible, consistent with the development of an adequate decisional record.

The following procedures should be observed in the conduct of public hearings:

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(a) Preliminary:

(1) A verbatim transcript will be made of the hearing.

(2) The Chairman should convene the hearing by stating the title of the proceeding and describing its nature.

(3) He should state the date, time, and place at which the prehearing conferences were held, and identify the persons participating in them. He should summarize the second prehearing conference order.

(4) He should explain the procedures for the conduct of the hearing. He should request that counsel for the parties identify themselves on the record, and provide them with the opportunity to make opening statements of their respective positions.

(5) He should describe, for the benefit of members of the public who may be present, the respective roles of the board, the ACRS and the staff, and the Commission procedures for review of the decision. He should also describe the continuing review and inspection surveillance conducted by the Commission after a construction permit or an operating license has been issued.

(b)(1) The Chairman should call attention to the provisions of § 2.715 for participation by limited appearance. He should briefly explain these provisions and the rights of persons who are permitted to make limited appearances.

(2) The Chairman should inquire of those in attendance whether there are any who wish to participate in the hearing by limited appearance.

(3) Should any person seek leave to intervene when the hearing has been convened, he must set forth, with particularity in a written petition, the reasons why it was not possible to file a petition within the time prescribed in the notice of hearing, as described in Section III, to afford a basis for the board to determine whether or not good cause has been shown for the untimely filing. In granting a petition for leave to intervene which is not timely filed, the board will impose such conditions as are appropriate to minimize any delay in the proceeding.

(4) A person making a limited appearance may want not only to state his position, but to raise questions which he would like to have answered. This should be permitted to the extent the questions are within the scope of the proceeding as defined by the issues set out in the notice of hearing, the prehearing conference order, and any later orders. Usually such persons should be asked to make their statements and raise their questions early in the proceeding so that the board will have an opportunity to be sure that relevant and meritorious questions are properly dealt with during the course of the hearing.

7 FR 15127

(5) It is the Commission's view that the rules governing intervention and limited appearances are necessary in the interest of orderly proceedings. The Commission also believes that through these two methods of public participation all members of the public are assured of the right to participate by a method appropriate to their interest in the matter. This should be fully explained at the beginning of the hearing. In some cases the board may feel that it must deny an application to intervene but that it can still accommodate the desire of the person involved by allowing him to make a statement and raise questions under the limited appearance rule.

(6) Boards have considerable discretion as to the manner in which they accommodate their conduct of the hearing to local public interest and the desires of local citizens to be heard. Particularly in cases where it is evident that there is local concern as to the safety of the proposed plant, boards should so conduct the hearing as to give appropriate opportunity for local citizens to express their views, while at the same time protecting the legal interests of all parties and the public interest in an orderly and efficient licensing process.

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(7) In some cases, argument and further hearing can add nothing to the filings of the parties. In those cases the board is authorized, pursuant to § 2.749, on motion, to render a decision, if the filings in the proceeding and other materials show that there is no genuine issue as to any material fact. However, in proceedings involving construction permits, this procedure may be used only for determining subordinate issues and not the ultimate issues as to whether the construction permit should be issued.

(c) Opening statements:

(1) It is anticipated that the applicant, who has the burden of proof, will, at an appropriate time early in the proceeding, make an oral statement describing in terms that will be readily understood by the public, the principal safety and environmental considerations involved in carrying out the activity sought to be authorized.

(2) Other parties to the proceeding may also make an oral opening statement describing their position on the proposed licensing action.

(d) Evidence:

(1) Pursuant to § 2.732, the applicant has the burden of proof.

(2) The parties are required to submit direct testimony in written form and serve copies of such prepared written testimony on all parties pursuant to the schedule established at the second prehearing conference—in any event, at least 15 days in advance of the session of the hearing at which such testimony is to be presented, as provided by § 2.743(b), unless the board orders otherwise on the basis of objections presented. The staff's position is reflected primarily in the safety evaluation and final environmental impact statement. Consequently, the staff will not present its case until these documents are available. The use of such advance written testimony is expected to expedite the hearing process.

49 FR 9352

(3) The testimony of all witnesses will be given under oath. These witnesses may be collectively sworn at the opening of the hearing or if additional witnesses are called upon to testify at a subsequent stage they may be sworn at the time of their appearance. There is ordinarily no need for oral recital of prepared testimony unless the Board considers that some useful purpose will be served.

(4) The proceedings should be conducted as expeditiously as practicable, without impairing the development of a clear and adequate record. The order of presenting testimony may be freely varied in the conduct of the hearing. The Board may find it helpful to take expert testimony from witnesses on a roundtable basis after the receipt in evidence of prepared testimony.

(5) To prevent unnecessary delays and an unnecessarily large record, the Board may, pursuant to § 2.757, limit cumulative testimony, strike argumentative, repetitious, cumulative, or irrelevant evidence, take other necessary and proper steps to prevent argumentative, repetitious or cumulative cross examination, and impose appropriate time limitations on arguments.

(6) Documentary evidence may be offered in evidence as provided in § 2.743. Such evidence offered during the course of the hearing should be described by counsel, and furnished to the reporter for marking. Documents offered for marking should be numbered in order of receipt. On identification of a document, it may be offered in evidence.

(7) Objections may be made by counsel to any questions or any line of questioning, and to the admission of any document and should be ruled upon by the board. The board may admit the evidence, may sustain the objection, or may receive the evidence, reserving for later determination the question of admissibility. In passing on objections, the board, while not bound to view proferred evidence according to its admissibility under strict application of the rules of evidence in judicial proceedings, should exclude evidence that is irrelevant to issues in the case as defined in the notice of hearing or the prehearing conference order, or that pertains to matters outside the jurisdiction of the board or the Nuclear Regulatory Commission. Irrelevant material in prepared testimony submitted in advance under § 2.743(b) may be subject to a motion to strike under the procedures provided in § 2.730.

(8) Use of scientifically or technically trained persons who are not attorneys to conduct direct or cross-examination on behalf of a party is provided for in § 2.733. This procedure is a privilege, not a right,

37 FR 15127

and may be granted to further the conduct of the hearing. Before permitting such a person to conduct examination of witnesses, the board must determine (i) that he has technical or scientific qualifications, (ii) that he has read the written testimony and any documents which are to be the subject of his examination, and (iii) that he has prepared himself to conduct a meaningful and expeditious examination. Permission to conduct examination will be limited to the areas in which the interrogator is shown to be qualified. The party on whose behalf the interrogator conducts the examination and his attorney are responsible for the interrogator's conduct of examination or cross-examination.

(9) The extent to which challenges to NRC regulations can be made in a licensing proceeding is limited. A party may petition for waiver of or exception to the application of a specified NRC rule or regulation to an aspect of the subject matter of the proceeding. The party must file a petition and an affidavit that identifies the specific aspect of the subject matter of the proceeding as to which application of the rule or regulation would not serve the purpose for which the regulation was adopted and that sets forth with particularity the special circumstances alleged to justify a waiver or exception on that ground (§ 2.758). Upon a finding by the board, based on the petition and affidavits and any material submitted by other parties, that the party has not made a prima facie case, no evidence, discovery, or argument will be allowed on the matter. If the Board finds that such a showing has been made, it will certify the matter, without ruling, directly to the Commission for a determination as to whether the application of the regulation to a particular aspect of the subject matter of the proceeding should be waived or an exception made. 37 FR 15127

(10) The Commission has recognized the public interest in achieving fair and reasonable settlement of contested proceedings (§ 2.759). Therefore, to the extent not inconsistent with the Act, fair and reasonable settlements are encouraged, either as to particular issues in a proceeding or the entire proceeding.

(11) Unless testimony is being taken on a roundtable basis or there is some occasion for clarification of testimony as rendered, the board may wish to reserve its questions until the parties have completed questioning of the witnesses, since counsel for the respective parties will generally be prepared to develop the various lines of pertinent questions.

(12) Conferences for the clarification of matters between the board and the parties, or the formulation of more meaningful questions, may be used to expedite the hearing and simplify the record. Informal conferences, including telephone conferences, should be encouraged to this end.

(13) The board should ordinarily not adjourn the hearing once it has begun, except as the hearing may be divided into segments to permit consideration of discrete areas, such as (i) radiological health and safety or (ii) environmental impact. To the extent practicable, legal questions should be resolved prior to the hearing. If the board believes that additional information is required in the presentation of the case, it would be expected to request the applicant or other party to supplement the presentation. If a recess should prove necessary to obtain such additional evidence, the recess should ordinarily be postponed until available evidence has been received.

(14) Many of the time limitations prescribed in Part 2 were set to allow the maximum time for the parties to the proceedings to perform various activities. Where the activities covered by the limitations can be performed in less time, the time limits may be reduced by order of the board, if appropriate, where such action would not prejudice a party. Similarly, in any case in which a time limit is not set by Part 2, the board should impose reasonable time limits.

(e) Record:

(1) The transcript of testimony and the exhibits, together with all of the papers and requests filed in a proceeding, constitute the record for decision, except to the extent that official notice is taken.

(2) Generally speaking, a decision by a board must be made on the basis of evidence which is in the record of the proceeding. A board, however, is expected to use its expert knowledge and experience in evaluating and drawing conclusions from the evidence that is in the record. The board may also take account of and rely on certain facts which do not have to be "proved" since they are "officially noticed"; these facts do not have to be "proved" since they are matters of common knowledge. Pursuant to § 2.743(i) "official notice" may be taken of any fact of which judicial notice might be taken by the courts of the United States and of any technical or scientific fact within the knowledge of the Commission as an expert body. Each fact officially noticed must be specified in the record with sufficient particularity to advise the parties of the matters which have been noticed or brought to the attention of the parties before the final decision, and each party adversely affected by the decision must be afforded an opportunity to controvert the noticed fact. (For example, a board might take "official notice" of the fact that high level wastes are encountered mainly as liquid residue from fuel reprocessing plants.) Matters which are "officially noticed" by a board furnish the same basis for findings of fact as matters which have been placed in evidence and proved in the usual sense. 37 FR 15127

(f) Participation by board members.

(1) In contested proceedings, the board will determine controverted matters as well as decide whether the findings required by the Act and the Commission's regulations should be made and whether, in accordance with Subpart A of Part 51, the construction permit should be issued as proposed.

Thus, in such proceedings, the board will determine the matters in controversy and may be called upon to make technical judgments of its own on those matters. As to matters pertaining to radiological health and safety which are not in controversy, boards are neither required nor expected to duplicate the review already performed by the staff and ACRS, and they are authorized to rely upon the testimony of the staff, the applicant, and the conclusions of the ACRS, which are not controverted by any party. 49 FR 9352

(2) In an uncontested case, boards are neither required nor expected to duplicate the radiological safety review already performed by the staff and the ACRS and they are authorized to rely upon the testimony of the staff and the applicant, and the conclusions of the ACRS. The role of the board is not to conduct a de novo evaluation of the application, but rather to decide whether the application and the record of the proceeding contain sufficient information, and the review of the application by the Commission's staff, including the environmental review pursuant to the National Environmental Policy Act of 1969, has been adequate, to support the findings proposed to be made by the Director of Regulation and the issuance of the construction permit proposed by the Director of Regulation. In doing so, the board is expected to be mindful of the fact that it is the applicant, not the staff, who is the proponent of the construction permit and who has the burden of proof. 37 FR 15127

(3) Whether the construction permit proceeding is contested or uncontested, the board will, as to environmental impact matters, (a) determine whether the requirements of section 102(2) (A), (C) and (E) of the National Environmental Policy Act of 1969 and Subpart A of Part 51 of this chapter have been complied with; (b) independently consider the final balance among conflicting factors contained in the record, with a view to determining the appropriate action to be taken; and (c) determine whether the construction permit should be granted, denied, or appropriately conditioned to protect environmental values. 49 FR 9352

(4) A question may be certified to the Commission or the Appeal Board, as appropriate, for determination when a major or novel question of policy, law or procedure is involved which cannot be resolved except by the Commission or the Appeal Board and when the prompt and final decision of the question is important for the protection of the public interest or to avoid undue delay or serious prejudice to the interests of a party. For example, a board may find it appropriate to certify novel questions as to the regulatory jurisdiction of the Commission or the right of persons to intervene.

(g) Close of hearing:

(1) If, at the close of the hearing, the board should have uncertainties with respect to the matters in controversy because of a need for a clearer understanding of the evidence which has already been presented, it is expected that the board would normally invite further argument from the parties—oral or written or both—before issuing its initial decision. If the uncertainties arise from lack of sufficient information in the record, it is expected that the board would normally require further evidence to be submitted in writing with opportunity for the other parties to reply or reopen the hearing for the taking of further evidence, as appropriate. If either of such courses is followed, it is expected that the applicant would normally be afforded the opportunity to make the final submission.

(2) A board should give each party the opportunity to make a brief closing statement. 37 FR 15127

(3) A schedule should be set by the board and recorded, either in the transcript or by written order, of the dates upon which the parties are directed by the board to file proposed findings of fact and conclusions of law. In uncontested cases, the proposed findings will ordinarily be extremely brief. In contested proceedings, proposed findings of fact and conclusions of law submitted by the parties may be more detailed. While brevity in such submissions is encouraged, the proposed findings and conclusions should be such as to reflect the position of parties submitting them, and the technical and factual basis therefor. 37 FR 24736

(4) The board should dispose of any additional procedural requests.

(5) The chairman should formally close the hearing. 43 FR 7209

VI. Posthearing Proceedings, Including the Initial Decision

(a) A board, acting through the Chairman, should dispose of procedural requests made after the close of the hearing, including motions of the parties for correction of the transcript. Responses to requests and motions of the parties are made part of the record by issuance of written orders.

(b) On receipt of proposed findings and conclusions from the parties, the board should prepare the initial decision. Under the Administrative Procedure Act and the Commission's regulations, the decision should include:

(1) Findings, conclusions, and rulings, with the reasons or basis for them, on all material issues of fact, law, or discretion presented on the record;

(2) All facts officially noticed and relied on, if any, in making the decision;

(3) The appropriate ruling, order, or denial or relief, with the effective date and time within which a notice of appeal from the initial decision may be filed;

(4) The time when the decision becomes final.

(c) Issues to be decided by the board:

(1) In a contested proceedings for the issuance of a construction permit, the board will determine the following issues:

(i) Whether in accordance with the provisions of, § 50.35(a) of this chapter:

(a) The applicant has described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features or components incorporated therein for the protection of the health and safety of the public;

(b) Such further technical or design information as may be required to complete the safety analysis and which can reasonably be left for later consideration, will be supplied in the final safety analysis report;

(c) Safety features or components, if any, which requires research and development have been described by the applicant and the applicant has identified, and there will be conducted, a research and development program reasonably designed to resolve any safety questions associated with such features and components; and

(d) On the basis of the foregoing, there is reasonable assurance that

(1) Such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and

(2) Taking into consideration the site criteria contained in Part 100 of this chapter, the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

(ii) Whether the applicant is technically qualified to design and construct the proposed facility;

(iii) Whether the applicant is financially qualified to design and construct the proposed facility; except that this subject shall not be an issue if the applicant is an electric utility seeking a license to construct a production or utilization facility of the type described in § 50.21(b) or 50.22;

(iv) Whether the issuance of a permit for the construction of the facility will be inimical to the common defense and security or to the health and safety of the public;

(v) Whether, with respect to the requirements of section 102(2) (A), (C) and (E) of the National Environmental Policy Act, in accordance with Subpart A of Part 51 of this chapter, the construction permit should be issued as proposed.

(2) In an uncontested proceeding for the issuance of a construction permit, the board will, without conducting a de novo evaluation of the application, determine:

(i) Whether the application and the record of the proceeding contain sufficient information, and the review of the application by the Commission's staff has been adequate, to support the findings proposed to be made and required by the Act for the issuance of the construction permit proposed by the Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate, and

(ii) Whether the review conducted pursuant to the National Environmental Policy Act of 1969 has been adequate.

(3) Regardless of whether the proceeding is contested or uncontested, the board will, in its initial decision, in accordance with Subpart A of Part 51 of this chapter:

(i) Determine whether the requirements of section 102(2)(A), (C) and (E) of the National Environmental Policy Act and Subpart A of Part 51 of this chapter have been complied with in the proceeding;

(ii) Independently consider the final balance among conflicting factors contained in the record of the proceeding with a view to determining the appropriate action to be taken; and

(iii) Determine whether the construction permit should be issued, denied, or appropriately conditioned to protect environmental values.

(d) It is expected that ordinarily a board will render its initial decision within 35 days after its receipt of proposed findings of fact and conclusions of law filed by the parties in a contested case and within 15 days after receipt of such proposed findings and conclusions in an uncontested case.

(e) The initial decision will be transmitted to the Chief, Docketing and Service Section, Office of the Secretary, for issuance.

(f) After the board's initial decision is issued, the entire record of the hearing, including the board's initial decision, will be sent to the Commission or the Appeal Board, as appropriate, for review. In the course of this review, the Commission may allow the board's decision to become the final decision of the Commission, may modify a board decision, or may send the case back to the board for additional testimony on particular points or for further consideration of particular issues.

VII. General

(a) Two members, being a majority of the board, constitute a quorum, if one of those members is the member qualified in the conduct of administrative proceedings. The vote of a majority controls in any decision by a board, including rulings during the course of a hearing as well as formal orders and the initial decision. A dissenting member is of course, free to express his dissent and the reasons for it in a separate opinion for the record.

(b) The Commission or the Chairman of the Atomic Safety and Licensing Board Panel may designate a technically qualified alternate or an alternate qualified in the conduct of administrative proceedings, or both, for a board. The designation of an alternate is discretionary. Alternates may be designated where the Commission (or the Chairman of the Atomic Safety and Licensing Board Panel) in its judgment believes that a proceeding involves factors that warrant the continuing assignment and presence of an alternate. If any alternates are designated before the hearing, they will receive copies and become familiar with the application and other documents filed by the parties prior to the start of the hearing. It is expected that an alternate will be constituted or appointed by the Commission or the Chairman of the Atomic Safety and Licensing Board Panel as a member of the board in situations where a technically qualified member of the board, or the member qualified in the conduct of administrative proceedings, becomes unavailable.

(c) Sections 2.719 and 2.780 specify the conditions on which there is permitted to be consultation between Commissioners and boards, on the one hand, and the staff, on the other hand, in initial licensing proceedings other than contested proceedings. Section 2.719 also permits a board, in the same type of proceeding, to consult with members of the panel from which members of the boards are drawn. Except for consultation by a board with the Chairman or Vice Chairman of the Atomic Safety and Licensing Board Panel, it is expected that such consultation by a board, when it occurs, will relate to specific technical matters rather than to matters of broad policy.

Such intraagency consultation and communications are not permitted in contested proceedings. A board may, however, obtain information from the Chairman or Vice Chairman of the Atomic Safety and Licensing Board Panel for the purpose of identifying relevant decisions or statements of Commission policy. It should also be noted that the provisions of § 2.780 prohibiting intraagency consultation and communication in contested proceedings are not applicable to matters certified to the Commission or to the Atomic Safety and Licensing Appeal Board under the Commission's rules in §§ 2.720(h) and 2.744(e), since those matters are not deemed to involve substantive matters at issue in a proceeding on the record.

VIII. Procedures Applicable to Operating License Proceedings

(a) This section sets out certain differences in procedure from those described in sections I–VII above, which are required by the fact that the proceeding is for the issuance of an operating license rather than a construction permit. Otherwise, the provisions of sections I through VII of this statement of general policy also apply to an operating license proceeding, except as the context requires otherwise.

44 FR 67088

(b) In an operating license proceeding the board will determine the matters in controversy among the parties, and where the board determines that a serious safety, environmental, or common defense and security matter was not raised by the parties, the board will determine such matter as being among the issues to be decided. Those issues will be specified in the notice of a hearing issued by the Commission, or in a prehearing conference order issued by the board in the exercise of its discretion during the hearing.

40 FR 2973

The issues will be the matters in controversy among the parties or raised by the board within the purview of the following:

37 FR 15127

(1) Whether there is reasonable assurance that construction of the facility will be substantially completed, on a timely basis, in conformity with the construction permit and the application as amended, the provisions of the Act, and the rules and regulations of the Commission;

(2) Whether the facility will operate in conformity with the application as amended, the provisions of the Act, and the rules and regulations of the Commission;

(3) Whether there is reasonable assurance (i) that the activities to be authorized by the operating license can be conducted without endangering the health and safety of the public, and (ii) that such activities will be conducted in compliance with the Commission's regulations;

49 FR 35747

(4) Whether the applicant is technically and financially qualified to engage in the activities to be authorized by the operating license in accordance with the Commission's regulations, except that the issue of financial qualification shall not be considered by the board if the applicant is an electric utility seeking a license to operate a utilization facility of the type described in § 50.21(b) or § 50.22.

37 FR 15127

(5) Whether the applicable provisions of 10 CFR Part 140 have been satisfied;

(6) Whether issuance of the license will be inimical to the common defense and security or to the health and safety of the public; and

49 FR 935

(7) Whether, with respect to the requirements of section 102(2) (A), (C), and (E) of the National Environmental Policy Act, in accordance with Subpart A of Part 51, the operating license should be issued as proposed.

40 FR 2973

(c) The board, in operating license proceedings, will make findings on the matters in controversy among the parties and any matter not raised by the parties but examined by the board in its discretion in accordance with paragraph (b) of this section and § 2.760a. Depending on the resolution of those matters, the Director of Regulation would issue, deny, or appropriately condition the operating license.

37 FR 15127

(d) In operating license proceedings, the procedure for summary disposition of the proceeding on the pleadings described in § 2.749 may be used to determine the ultimate issue of whether the operating license should be issued.

40 FR 2973

IX. LICENSING PROCEEDINGS SUBJECT TO APPELLATE JURISDICTION OF ATOMIC SAFETY AND LICENSING APPEAL BOARD

(a) An Atomic Safety and Licensing Appeal Board, composed of three members assigned from the Atomic Safety and Licensing Appeal Panel, designated by the Commission, reviews initial decisions of presiding officers in (1) proceedings on applications under Part 50 for facility licenses or construction permits and (2) such other licensing proceedings as the Commission specifies. In such proceedings, an Atomic Safety and Licensing Appeal Board performs the functions and exercises the authority of the Commission described in sections I(e), V(f)(4), and VI(f), except as their context may require otherwise. The Atomic Safety and Licensing Appeal Board is required to decide each matter before it in accordance with the rules and regulations, case precedent, and established policies of the Commission.

44 FR 67088

In a proceeding on an application for an operating license, if the Atomic Safety and Licensing Appeal Board determines that a serious safety, environmental, or common defense and security matter has not been raised by the parties, it has the authority to give appropriate consideration to that matter.

40 FR 2973

It has no responsibility or authority for issuing rules or regulations. The Appeal Board for a particular proceeding is composed of three members assigned from the Atomic Safety and Licensing Appeal Panel and possessing qualifications deemed appropriate to the issues to be decided. The Chairman of the Appeal Board for a particular proceeding shall be qualified in the conduct of administrative proceedings.

34 FR 13360

(b) Two members, being a majority of the Appeal Board, constitute a quorum, if one of those members is the member qualified in the conduct of administrative proceedings.

37 FR 17159

Except as permitted by § 2.787(b), the vote of a majority controls in any decision by the Appeal Board, including orders in interlocutory matters and final decisions.

34 FR 13360

A dissenting member is, of course, free to express his dissent and the reasons for it in a separate opinion for the record.

37 FR 22791

(c) Consultation between members of the Atomic Safety and Licensing Appeal Board for a particular proceeding and the staff, in initial licensing proceedings other than contested proceedings, is permitted on the conditions specified for the Commissioners under 10 CFR 2.780. However, members of atomic safety and licensing boards for particular proceedings shall not consult, on any fact in issue in those proceedings—whether contested or uncontested—with members of the Appeal Board Panel.

48 FR 52282

(d)(1) Appeals to the Appeal Board from initial decisions, or designated portions thereof, are initiated by the filing of a notice of appeal within 10 days of the issuance and service of the initial decision.

(2) A brief in support of the appeal must be filed by the appellant within 30 days thereafter (40 days in the case of the staff).

(3) A responsive brief may be filed by any other party within 30 days (40 days in the case of the staff) after the period has expired for the filing and service of the briefs of all appellants. A responding party shall file a single responsive brief regardless of the number of appellant's briefs filed. The prescribed time limits are subject to being lengthened or shortened in a particular case, either on motion of a party or by the Appeal Board on its own initiative (10 CFR 2.711). The time limits are also subject to the provisions of 10 CFR 2.710 relating to service by mail.

(4) There must be strict compliance with the time limits prescribed for the filing of the notice of appeal and briefs by the rules of practice or by an order of the Appeal Board which extends or shortens those limits in the particular case. Absent a showing of extraordinary and unanticipated circumstances, motions for extensions of time must be received by the Appeal Board at least 1 day prior to the date upon which the document in question is then due for filing. In no circumstances will a document be accepted by the Appeal Board on an untimely basis unless it is accompanied by a motion for leave to file it out of time, which similarly must be founded upon extraordinary and unanticipated circumstances.

(5) Every brief in excess of 10 pages shall contain a table of contents, with page references, and a table of cases (alphabetically arranged), statutes, regulations, and other authorities cited with references to the pages of the brief where they are cited.

(6) No brief is to exceed 70 pages in length unless leave to file a brief of a specified greater length has been previously sought and granted (10 CFR 2.762(e)). In this connection, inasmuch as the Appeal Board has available to it the entire record of the proceeding, extended quotations in a brief from the record are neither required nor desirable. A summary is preferable, accompanied by explicit references to the record sources.

(7) Notices of appeal and briefs which in form or content are not in substantial compliance with the requirements imposed by the rules of practice are subject to being stricken.

(e) The holding of oral argument, whether or not specifically requested by a party, is within the Appeal Board's discretion (10 CFR 2.763). Where a notice of appeal has been filed, the Appeal Board routinely will consider whether the case should be calendared for oral argument. This consideration normally will take place following the receipt of all briefs. Oral argument will be directed if at least one member of the Appeal Board votes in favor of it. If oral argument is to be held, an order will be issued by the Appeal Board which will set the specific date and location, as well as the time allotted to each of the parties. In some instances, the order may also restrict the scope of the oral argument to one or more specified issues. It is anticipated that oral arguments will be conducted in either Washington, D.C., or Bethesda, Md. 48 FR 52282

X. Proceedings for the Consideration of Antitrust Aspects of Facility License Applications

(a) Under the Atomic Energy Act of 1954, as amended, the Commission is required, with respect to applications for construction permits or operating licenses for production and utilization facilities for industrial or commercial purposes licensed under section 103, which include power reactors subject to the mandatory hearing requirements of section 189a of the Act, to follow procedures for antitrust review in section 105c of the Act. This section outlines the procedures used by the Commission to implement that section.

(b)(1) When the antitrust information portion of an application is received and docketed for a facility construction permit under section 103 of the Act which is subject to antitrust review under section 105c, the notice of receipt of the antitrust information published in the Federal Register shall state that persons who wish to have their views on the antitrust aspects of the application considered by the NRC and presented to the Attorney General for consideration shall submit such views to the Commission within sixty (60) days after publication of the notice. 47 FR 9983

(2) Upon receipt of the antitrust information responsive to Regulatory Guide 9.3 submitted in connection with an application for a facility operating license under section 103 of the Act, the Director of Nuclear Reactor Regulation or the Director of Nuclear Material Safety and Safeguards, as appropriate, shall publish in the Federal Register and in appropriate trade journals a "Notice of Receipt of Operating License Antitrust Information." The notice shall invite persons to submit, within thirty (30) days after publication of the notice, comments or information concerning antitrust aspects of the application to assist the Director in determining, pursuant to section 105c of the Act, whether significant changes in the licensee's activities or proposed activities have occurred since completion of the previous antitrust review in connection with the construction permit application. The notice shall also state that persons who wish to have their views on the antitrust aspects of the application considered by the NRC and presented to the Attorney General for consideration should submit such views within thirty (30) days after publication of the notice to: U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Chief, Antitrust and Economic Analysis Branch.

(3) If the Director of Nuclear Reactor Regulation or the Director of Nuclear Material Safety and Safeguards, as appropriate, after reviewing any comments or information received in response to the published notice and any comments or information regarding the applicant received from the Attorney General, concludes that there have been no significant changes since the completion of the previous antitrust review in connection with the construction permit, a finding of no significant changes shall be published in the Federal Register, together with a notice stating that any request for reevaluation of such finding should be submitted within thirty (30) days of publication of the notice. If no requests for reevaluation are received within that time, the finding shall become the NRC's final determination. Requests for a reevaluation of the no significant changes determination shall be accepted after the date when the Director's finding becomes final but before the issuance of the OL only if they contain new information, such as information about facts or events of antitrust significance that have occurred since that date, or information that could not reasonably have been submitted prior to that date. 47 FR 9983

(4) If, as a result of the reevaluation of the finding described above, it is determined that there have been no significant changes, the Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate, shall deny the request and shall publish a notice of finding of no significant changes in the Federal Register. The notice and finding become the final NRC decision thirty (30) days after being made and only in the event that the Commission has not exercised sua sponte review.

(5) If the Director of Nuclear Reactor Regulation or the Director of Nuclear Material Safety and Safeguards, as appropriate, concludes that significant changes have occurred since the completion of the previous antitrust review in connection with the construction permit, then the provisions of § 2.102(d) shall apply.

(c)(1) Except as provided in paragraph (c)(2) below, the Director of Nuclear Reactor Regulation or the Director of Nuclear Material Safety and Safeguards, as appropriate, shall refer and transmit a copy of each application for a construction permit or an operating license for a utilization or production facility under section 103 of the Act, to the Attorney General as required by section 105c of the Act. Under that section, the Attorney General will, within a reasonable time, but in no event to exceed 180 days after receipt, render such advice to the Commission as is determined to be appropriate in regard to the finding to be made by the Commission as to whether the activities under the license would create or maintain a situation inconsistent with the antitrust laws specified in subsection 105a of the Act.

(2) The review by the Attorney General described in paragraph (c)(1) above is not required for applications for operating licenses for production or utilization facilities under section 103 of the Act for which the construction permit was also issued under section 103, unless the Director of Nuclear Reactor Regulation or the Director of Nuclear Material Safety and Safeguards, as appropriate, determines, after consultation with the Attorney General and in accordance with § 2.101(e), that such review is advisable on the ground that significant changes in the licensee's activities or proposed activities have occurred subsequent to the previous review by the Attorney General and by the Commission under section 105c of the Act in connection with the construction permit. 47 FR 9983

(d) The Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate, will publish the Attorney General's advice in the Federal Register promptly upon receipt, and will make such advice a part of the record in any proceeding on antitrust matters conducted in accordance with subsection 105c(5) and section 189a of the Act. The Director of Regulation will also publish in the Federal Register a notice that the Attorney General has not rendered any such advice. The notice published in the Federal Register will also include a notice of hearing, if appropriate, or, if the Attorney General has not recommended a hearing, will state that any person whose interest may be affected by the proceeding may, pursuant to and in accordance with § 2.714, file a petition for leave to intervene and request a hearing on the antitrust aspects of the application. The notice will state that petitions for leave to intervene and requests for hearing shall be filed within 30 days after publication of the notice.

(e) If a hearing on antitrust aspects of the application is requested, or is recommended by the Attorney General, it will generally be held separately from the hearing held on matters of radiological health and safety and common defense and security described in sections I-VIII of this appendix. The notice of hearing will fix a time for the hearing, which will be as soon as practicable after the receipt of the Attorney General's advice and compliance with section 189a of the Act and other provisions of this part. However, as permitted by subsection 105c(8) of the Act, with respect to proceedings in which an application for a construction permit was filed prior to December 19, 1970, and proceedings in which a written request for antitrust review of an application for an operating license to be issued under section 104b has been made by a person who intervened or sought by timely written notice to the Commission to intervene in the construction permit proceeding for the facility to obtain a determination of antitrust consideration or to advance a jurisdictional basis for such determination within 25 days after the date of publication in the Federal Register of notice of filing of the applica- 37 FR 15127

37 FR 15127 tion for an operating license or December 19, 1970, whichever is later, the Commission may issue a construction permit or operating license, provided that the permit or license so issued contains the condition specified in § 50.55b of this chapter.

46 FR 55083 **(f) Hearings on antitrust aspects will be conducted by a presiding officer, either an Administrative Law Judge or an atomic safety and licensing board comprised of three members, one of whom will be qualified in the conduct of administrative proceedings and two of whom will have such technical or other qualifications as the Commission deems appropriate to the issues to be decided.**

35 FR 19655 (g) When the Attorney General has advised that there may be adverse antitrust aspects and recommends that a hearing be held, the Attorney General or his designee may participate as a party in the proceedings.

46 FR 55083 **(h) At the hearing, the presiding officer will give due consideration to the advice received from the Attorney General and to evidence pertaining to antitrust aspects received at the hearing.**

(i) The presiding officer will, in the initial decision, make a finding as to whether the activities under the proposed license would create or maintain a situation inconsistent with the antitrust laws as specified in section 105a of the Act. If the presiding officer finds that such a situation would be created or maintained, it will consider, in determining whether the permit or license should be issued or continued, such other factors as it deems necessary to protect the public interest, including the need for power in the affected area. The certainty of contravening the antitrust laws or the policies clearly underlying these laws is not intended to be implicit in this standard; nor is mere possibility of inconsistency. The finding will be based on reasonable probability of contravention of the antitrust laws or the policies clearly underlying these laws. The presiding officer will conclude whether, in its judgment, it is reasonably probable that the activities under the license would, when the license is issued or thereafter, be inconsistent with any of the antitrust laws or the policies clearly underlying these laws.

(j) On the basis of the findings in the proceeding on the antitrust aspect of the application, the presiding officer may (i) authorize the issuance of the permit or license after favorable consideration of matters of radiological health and safety and common defense and security, and matters raised under the National Environmental Policy Act of 1969, at the hearing described in sections I–VIII of this appendix; (ii) authorize the continuation of a permit or license already issued; (iii) direct the denial of the application for the permit or license, or the rescission of a permit or license already issued; or (iv) authorize the issuance of a permit or license subject to appropriate conditions, and subject to favorable consideration of matters of radiological health and safety and common defense matters raised under the National Environmental Policy Act of 1969 at the hearing described in sections I–VIII of this appendix.

Appendix C—General Statement of Policy and Procedure for NRC Enforcement Actions

The following statement of general policy and procedure explains the enforcement policy and procedures of the U.S. Nuclear Regulatory Commission and its staff in initiating enforcement actions, and of presiding officers, the Atomic Safety and Licensing Appeals Board, and the Commission in reviewing these actions. This statement is applicable to enforcement in matters involving the public health and safety, the common defense and security, and the environment.[1]

I. Introduction and Purpose

The purpose of the NRC enforcement program is to promote and protect the radiological health and safety of the public, including employees' health and safety, the common defense and security, and the environment by:

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- Ensuring compliance with NRC regulations and license conditions;
- Obtaining prompt correction of violations;
- Deterring future violations; and
- Encouraging improvement of licensee performance, and by example, that of industry, including the prompt identification and reporting of potential safety problems.

Consistent with the purpose of this program, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which the NRC expects of its licensees. It is the Commission's intent that sanctions should be designed to ensure that a licensee does not deliberately profit from violations of NRC requirements. Each enforcement action is dependent on the circumstances of the case and requires the exercise of discretion after consideration of these policies and procedures. In no case, however, will licensees who cannot achieve and maintain adequate levels of protection be permitted to conduct licensed activities.

II. Statutory Authority and Procedural Framework

A. Statutory Authority

The NRC's enforcement jurisdiction is drawn from the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended.

Section 161 of the Atomic Energy Act authorizes NRC to conduct inspections and investigations and to issue orders as may be necessary or desirable to promote the common defense and security or to protect health or to minimize danger to life or property. Section 186 authorizes NRC to revoke licenses under certain circumstances (e.g., for material false statements, in response to conditions that would have warranted refusal of a license on an original application, for a licensee's failure to build or operate a facility in accordance with the terms of the permit or license, and for violation of a NRC regulation). Section 234 authorizes NRC to impose civil penalties not to exceed $100,000 per violation per day for the violation of certain specified licensing provisions of the Act, rules, orders, and license terms implementing these provisions, and for violations for which licenses can be revoked. In addition to the enumerated provisions in section 234, sections 84 and 147 authorize the imposition of civil penalties for violations of regulations implementing those provisions. Section 232 authorizes NRC to seek injunctive or other equitable relief for violation of regulatory requirements.

Section 206 of the Energy Reorganization Act authorizes NRC to impose civil penalties for knowing and conscious failures to provide certain safety information to the NRC.

Chapter 18 of the Atomic Energy Act provides for varying levels of criminal penalties (i.e., monetary fines and imprisonment) for willful violations of the Act and regulations or orders issued under Sections 65, 161(b), 161(i), or 161(o) of the Act. Section 223 provides that criminal penalties may be imposed on certain individuals employed by firms constructing or supplying basic components of any utilization facility if the individual knowingly and willfully violates NRC requirements such that a basic component could be significantly impaired. Section 235 provides that criminal penalties may be imposed on persons who interfere with inspectors. 49 FR 8583

Section 236 provides that criminal penalties may be imposed on persons who attempt to or cause sabotage at a nuclear facility or to nuclear fuel. Alleged or suspected criminal violations of the Atomic Energy Act are referred to the Department of Justice for appropriate action.

B. Procedural Framework

10 CFR Part 2, Subpart B, of NRC's regulations sets forth the procedures the NRC uses in exercising its enforcement authority. 10 CFR 2.201 sets forth the procedures for issuing notices of violation.

The procedure to be used in assessing civil penalties is set forth in 10 CFR 2.205. This regulation provides that the appropriate NRC Office Director initiates the civil penalty process by issuing a notice of violation and proposed imposition of a civil penalty. The licensee is provided an opportunity to contest in writing the proposed imposition of a civil penalty. After evaluation of the licensee's response, the Director may mitigate, remit, or impose the civil penalty. An opportunity is provided for a hearing if a civil penalty is imposed.

The procedure for issuing an order to show cause why a license should not be modified, suspended, or revoked or why such other action should not be taken is set forth in 10 CFR 2.202. The mechanism for modifying a license by order is set forth in 10 CFR 2.204. These sections of Part 2 provide an opportunity for a hearing to the affected licensee. However, the NRC is authorized to make orders immediately effective if the public health, safety or interest so requires or, in the case of an order to show cause, if the alleged violation is willful.

III. Severity of Violations

Regulatory requirements [2] have varying degrees of safety, safeguards, or environmental significance. Therefore, the relative importance of each violation must be identified as the first step in the enforcement process.

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[1] Antitrust enforcement matters will be dealt with on a case-by-case basis.

[2] The term "requirement" as used in this policy means a legally binding requirement such as a statute, regulation, license condition, technical specification, or order.

Consequently, violations are categorized in terms of five levels of severity to show their relative importance within each of the following eight activity areas:

Reactor Operations; Facility Construction; Safeguards; Health Physics; Transportation; Fuel Cycle and Materials Operations; Miscellaneous Matters; and Emergency Preparedness.

Licensed activities not directly covered by one of the above listed areas, e.g., export license activities, will be placed in the activity area most suitable in light of the particular violation involved. Within each activity area, Severity Level I has been assigned to violations that are the most significant and Severity Level V violations are the least significant. Severity Level I and II violations are of very significant regulatory concern. In general, violations that are included in these severity categories involve actual or high potential impact on the public. Severity Level III violations are cause for significant concern. Severity Level IV violations are less serious but are of more than minor concern; i.e., if left uncorrected, they could lead to a more serious concern. Severity Level V violations are of minor safety or environmental concern.

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Comparisons of significance between activity areas are inappropriate. For example, the immediacy of any hazard to the public associated with Severity Level I violations in Reactor Operations is not directly comparable to that associated with Severity Level I violations in Reactor Construction.

While examples are provided in Supplements I through VIII for determining the appropriate severity level for violations in each of the eight activity areas, the examples are neither exhaustive nor controlling.

These examples do not create new requirements. Each is designed to illustrate the significance which the NRC places on a particular type of violation of NRC requirements. Each of the examples in the supplements is predicated on a violation of a regulatory requirement.

In each case, the severity of a violation will be characterized at the level best suited to the significance of the particular violation. In some cases, violations may be evaluated in the aggregate and a single severity level assigned for a group of violations.

The severity level of a violation may be increased if the circumstances surrounding the matter involve careless disregard of requirements, deception or other indications of willfulness. The term "willfulness" as used here embraces a spectrum of violations ranging from deliberate intent to violate or falsify to and including careless disregard for requirements. Willfulness does not include acts which do not rise to the level of careless disregard, e.g., inadvertent clerical errors in a document submitted to the NRC. In determining the specific severity level of a violation involving willfulness, consideration will be given to such factors as the position of the person involved in the violation (e.g., first-line supervisor or senior manager), the significance of any underlying violation, the intent of the violator (i.e., negligence not amounting to careless disregard, careless disregard, or deliberateness), and the economic advantage, if any, gained as a result of the violation. The relative weight given to each of these factors in arriving at the appropriate severity level will be dependent on the circumstances of the violation.

The NRC expects licensees to provide full, complete, timely, and accurate information and reports. Accordingly, unless otherwise categorized in the Supplements, the severity level of a violation involving the failure to make a required report to the NRC will be based upon the significance of and the circumstances surrounding the matter that should have been reported. A licensee will not normally be cited for a failure to report a condition or event unless the licensee was actually aware of the condition or event which it failed to report. However, the severity level of an untimely report, in contrast to no report, may be reduced depending on the circumstances surrounding the matter.

IV. Enforcement Conferences

Whenever the NRC has learned of the existence of a potential violation for which a civil penalty or other escalated enforcement action may be warranted, the NRC will normally hold an enforcement conference with the licensee prior to taking enforcement action. The NRC may also elect to hold an enforcement conference for other violations, e.g., Severity Level IV violation which, if repeated, could lead to escalated enforcement action. The purpose of the enforcement conference is to: (1) Discuss the violations, their significance and causes, and the licensee's corrective actions, (2) determine whether there are any aggravating or mitigating circumstances, and (3) obtain other information which will help determine the appropriate enforcement action.

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In addition, during the enforcement conference, the licensee will be given an opportunity to explain to the NRC what corrective actions (if any) were taken or will be taken following discovery of the potential violation. Licensees will be told when a meeting is an enforcement conference. Enforcement conferences will not normally be open to the public.

When needed to protect the public health and safety or common defense and security, escalated enforcement action, such as the issuance of an immediately effective order modifying, suspending, or revoking a license will be taken prior to the enforcement conference. In such cases, an enforcement conference may be held after the escalated enforcement action is taken.

V. Enforcement Actions

This section describes the enforcement sanctions available to NRC and specifies the conditions under which each may be used. The basic sanctions are notices of violation, civil penalties, and orders of various types. Additionally, related administrative mechanisms such as bulletins and confirmatory action letters are used to supplement the enforcement program. In selecting the enforcement sanctions to be applied, NRC will consider enforcement actions taken by other Federal or State regulatory bodies having concurrent jurisdiction, such as in transportation matters. With very limited exceptions, whenever a violation of NRC requirements is identified, enforcement action is taken. The nature and extent of the enforcement action is intended to reflect the seriousness of the violation involved. For the vast majority of violations, action by an NRC regional office is appropriate in the form of a Notice of Violation requiring a formal response from the recipient describing its corrective actions. The relatively small number of cases involving elevated enforcement action receives substantial attention by the public, and may have significant impact on the licensee's operation. These elevated enforcement actions include civil penalties; orders modifying, suspending or revoking licenses; or orders to cease and desist from designated activities.

A. Notice of Violation

A notice of violation is a written notice setting forth one or more violations of a legally binding requirement. The notice normally requires the recipient to provide a written statement describing: (1) corrective steps which have been taken and the results achieved; (2) Corrective steps which will be taken to prevent recurrence; and (3) the date when full compliance will be achieved. NRC may require responses to notices of violations to be under oath. Normally, reponses under oath will be required only in connection with civil penalties and orders.

NRC uses the notice of violation as the standard method for formalizing the existence of a violation. A notice of violation is normally the only enforcement action taken, except in cases where the criteria for civil penalties and orders, as set forth in Sections IV.B and IV.C, respectively, are met. In such cases, the notice of violation will be issued in conjunction with the elevated actions.

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Because the NRC wants to encourage and support licensee initiative for self-identification and correction of problems, NRC will not generally issue a notice of violation for a violation that meets all of the following tests:

(1) It was identified by the licensee;
(2) It fits in Severity Level IV or V;
(3) It was reported, if required;
(4) It was or will be corrected, including measures to prevent recurrence, within a reasonable time; and
(5) It was not a violation that could reasonably be expected to have been prevented by the licensee's corrective action for a previous violation.

Licensees are not ordinarily cited for violations resulting from matters not within their control, such as equipment failures that were not avoidable by reasonable licensee quality assurance measures or management controls. Generally, however, licensees are held responsible for the acts of their employees. Accordingly, this policy should not be construed to excuse personnel errors. Enforcement actions involving individuals, including licensed operators, will be determined on a case-by-case basis and must be approved by the Director of the responsible Program Office.[3]

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[3] Section 234 of the Atomic Energy Act gives the Commission authority to impose civil penalties for violations on "any person." "Person" is broadly defined in Section 11s of the AEA to include individuals, a variety of organizations, and any representatives or agents. This gives the Commission authority to impose civil penalties on employees of licensees or on separate entities when a violation of a requirement directly imposed on them is committed.

B. Civil Penalty

A civil penalty is a monetary penalty that may be imposed for violation of: (a) Certain specified licensing provisions of the Atomic Energy Act or supplementary NRC rules or orders, (b) any requirement for which a license may be revoked, or (c) reporting requirements under Section 206 of the Energy Reorganization Act. Civil penalties are designed to emphasize the need for lasting remedial action and to deter future violations.

Generally, civil penalties are imposed for Severity Level I violations, are imposed absent mitigating circumstances for Severity Level II violations, are considered for Severity Level III violations, and may be imposed for Severity Level IV violations that are similar [4] to previous violations for which the licensee did not take effective corrective action.

In applying this guidance for Severity Level IV violations, NRC normally considers civil penalties only for similar Severity Level IV violations that occur after the date of the last inspection or within two years, whichever period is greater.

Civil penalties will normally be assessed for knowing and conscious violations of the reporting requirements of Section 206 of the Energy Reorganization Act, and for any willful violation of any Commission requirement including those at any severity level.

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NRC imposes different levels of penalties for different severity level violations and different classes of licensees. Tables 1A and 1B show the base civil penalties for various reactor, fuel cycle, and materials programs. The structure of these tables generally takes into account the gravity of the violation as a primary consideration and the ability to pay as a secondary consideration. Generally, operations involving greater nuclear material inventories and greater potential consequences to the public and licensee employees receive higher civil penalties. Regarding the secondary factor of ability of various classes of licensees to pay the civil penalties, it is not the NRC's intention that the economic impact of a civil penalty be such that it puts a licensee out of business (orders, rather than civil penalties, are used when the intent is to terminate licensed activities) or adversely affects a licensee's ability to safely conduct licensed activities. The deterrent effect of civil penalties is best served when the amounts of such penalties take into account a licensee's "ability to pay." In determining the amounts of civil penalties for licensees for whom the tables do not reflect the ability to pay, NRC will consider as necessary an increase or decrease on a case-by-case basis.

NRC attaches great importance to comprehensive licensee programs for detection, correction, and reporting of problems that may constitute, or lead to, violation of regulatory requirements. This is emphasized by giving credit for effective licensee audit programs when licensees find, correct, and report problems expeditiously and effectively. To encourage licensee self-identification and correction of violations and to avoid potential concealment of problems of safety significance, application of the adjustment factors set forth below may result in no civil penalty being assessed for violations which are identified, reported (if required), and effectively corrected by the licensee.

On the other hand, ineffective licensee programs for problem identification or correction are unacceptable. In cases involving willfulness, flagrant NRC-identified violations, repeated poor performance in an area of concern, or serious breakdown in management controls, NRC intends to apply its full enforcement authority where such action is warranted, including issuing appropriate orders and assessing civil penalties for continuing violations on a per day basis, up to the statutory limit of $100,000 per violation, per day. In this regard, while management involvement, direct or indirect, in a violation may lead to an increase in the civil penalty, the lack of such involvement may not be used to mitigate a civil penalty. Allowance of mitigation could encourage lack of management involvement in licensed activities and a decrease in protection of the public health and safety.

NRC reviews each proposed civil penalty case on its own merits and adjusts the base civil penalty values upward or downward appropriately. Tables 1A and 1B identify the base civil penalty values for different severity levels, activity areas, and classes of licensees. After considering all relevant circumstances, adjustments to these values may be made for the factors described below:

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1. *Prompt Identification and Reporting.* Reduction of up to 50% of the base civil penalty may be given when a licensee identifies the violation and promptly reports the violation to the NRC. In weighing this factor, consideration will be given to, among other things, the length of time the violation existed prior to discovery, the opportunity available to discover the violation, the ease of discovery and the promptness and completeness of any required report. No consideration will be given to this factor if the licensee does not take immediate action to correct the problem upon discovery.

2. *Corrective Action to Prevent Recurrence.* Recognizing that corrective action is always required to meet regulatory requirements, the promptness and extent to which the licensee takes corrective action, including actions to prevent recurrence, may be considered in modifying the civil penalty to be assessed. Unusually prompt and extensive corrective action may result in reducing the proposed civil penalty as much as 50% of the base value shown in Table 1. On the other hand, the civil penalty may be increased as much as 50% of the base value if initiation of corrective action is not prompt or if the corrective action is only minimally acceptable. In weighing this factor, consideration will be given to, among other things, the timeliness of the corrective action, degree of licensee initiatives, and comprehensiveness of the corrective action—such as whether the action is focused narrowly to the specific violation or broadly to the general area of concern.

3. *Past Performance.* Reduction by as much as 100% of the base civil penalty shown in Table 1 may be given for prior good performance in the general area of concern. On the other hand, the base civil penalty may be increased as much as 100% for prior poor performance in the general area of concern.

In weighing this factor, consideration will be given to, among other things, the effectiveness of previous corrective action for similar problems, overall performance such as Systematic Assessment of Licensee Performance (SALP) evaluations for power reactors, and prior enforcement history including Severity Level IV and V violations in the area of concern. For example, failure to implement previous corrective action for prior similar problems may result in an increase in the civil penalty.

4. *Prior Notice of Similar Event.* The base civil penalty may be increased as much as 50% for cases where the licensee had prior knowledge of a problem as a result of a licensee audit, or specific NRC or industry notification, and had failed to take effective preventive steps.

5. *Multiple Occurrences.* The base civil penalty may be increased as much as 50% where multiple examples of a particular violation are identified during the inspection period.

The above factors are additive. However, in no instance will a civil penalty for any one violation exceed $100,000 per day.

The duration of a violation may also be considered in assessing a civil penalty. A greater civil penalty may be imposed if a violation continues for more than a day. For example:

(1) If a licensee is aware of the existence of a condition which results in an ongoing violation and fails to initiate corrective action, each day the condition existed may be considered as a separate violation and, as such, subject to a separate additional civil penalty.

(2) If a licensee is unaware of a condition resulting in a continuing violation, but clearly should have been aware of the condition or had an opportunity to correct the condition but failed to do so, a separate violation and attendant civil penalty may be considered for each day that the licensee clearly should have been aware of the condition or had an opportunity to correct the condition, but failed to do so.

(3) Alternatively, whether or not a licensee is aware or should have been aware of a violation that continues for more than one day, the civil penalty imposed for one violation may be increased to reflect the added significance resulting from the duration of the violation.

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The Tables and the mitigating factors determine the civil penalties which may be assessed for each violation. However, to focus on the fundamental underlying causes of a problem for which enforcement action appears to be warranted, the cumulative total for all violations which contributed to or were unavoidable consequences of that problem may be based on the amount shown in the table for a problem of that Severity Level, as adjusted. If an evaluation of such multiple violations shows that more than one fundamental problem is involved, each of which, if viewed independently, could lead to civil penalty action by itself, then separate civil penalties may be assessed for each such fundamental problem. In addition, the failure to make a required report of an event requiring such reporting is considered a separate problem and will normally be assessed a separate civil penalty, if the licensee is aware of the matter that should have been reported.

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[4] The word "similar," as used in this policy, refers to those violations which could have been reasonably expected to have been prevented by the licensee's corrective action for the previous violation.

Table 1A—Base Civil Penalties

	Plant operation, construction, health physics and EP	Safeguards	Transportation	
			Greater than type A quantity [1]	Type A quantity or less [2]
a. Power reactors	$100,000	$100,000	$100,000	$5,000
b. Test reactors	10,000	10,000	10,000	2,000
c. Research reactors & critical facilities	5,000	5,000	5,000	1,000
d. Fuel fabricators and industrial processors [3]	25,000	[4] 100,000	25,000	5,000
e. Mills and uranium conversion facilities	10,000		6,000	2,000
f. Industrial users of material [5]	10,000		5,000	2,000
g. Waste disposal licensees	10,000		5,000	2,000
h. Academic or medical institutions [6]	5,000		2,500	1,000
i. Other material licensees	1,000		2,500	1,000

[1] Includes irradiated fuel, high level waste, unirradiated fissile material, and any other quantities requiring Type B packaging.
[2] Includes low specific activity waste (LSA), low level waste, Type A packages, and excepted quantities and articles.
[3] Large firms engaged in manufacturing or distribution of byproduct, source, or special nuclear material.
[4] This amount refers to Category 1 licensees (as defined in 10 CFR 73.2(bb)). Licensed fuel fabricators not authorized to possess Category 1 material have a base penalty amount of $50,000.
[5] Includes industrial radiographers, nuclear pharmacies, and other industrial users.
[6] This applies to nonprofit institutions not otherwise categorized under sections "a" through "g" in this table.

Table 1B—Base Civil Penalties

[Base Civil Penalty Amount]

Severity Level	Percent of amount listed in Table 1A
I	100
II	80
III	50
IV	15
V	5

C. Orders

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An order is a written NRC directive to modify, suspend, or revoke a license; to cease and desist from a given practice or activity; or to take such other action as may be proper (*see* 10 CFR 2.202 and 2.204). Orders may be issued as set forth below. Orders may also be issued in lieu of, or in addition to, civil penalties, as appropriate.

(1) License Modification Orders are issued when some change in licensee equipment, procedures, or management controls is necessary.

(2) Suspension Orders may be used:

(a) To remove a threat to the public health and safety, common defense and security, or the environment;

(b) To stop facility construction when: (i) Further work could preclude or significantly hinder the identification or correction of an improperly constructed safety-related system or component, or (ii) the licensee's quality assurance program implementation is not adequate to provide confidence that construction activities are being properly carried out;

(c) When the licensee has not responded adequately to other enforcement action;

(d) When the licensee interferes with the conduct of an inspection or investigation; or

(e) For any reason not mentioned above for which license revocation is legally authorized.

Suspension may apply to all or part of the licensed activity. Ordinarily, a licensed activity is not suspended (nor is a suspension prolonged) for failure to comply with requirements where such failure is not willful and adequate corrective action has been taken.

(3) Revocation Orders may be used:

(a) When a licensee is unable or unwilling to comply with NRC requirements.

(b) When a licensee refuses to correct a violation.

(c) When a licensee does not respond to a notice of violation where a response was required.

(d) When a licensee refuses to pay a fee required by 10 CFR Part 170, or

(e) For any other reason for which revocation is authorized under Section 186 of the Atomic Energy Act (e.g., any condition which would warrant refusal of a license on an original application).

(4) Cease and Desist Orders are typically used to stop an unauthorized activity that has continued after notification by NRC that such activity is unauthorized.

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Orders are made effective immediately, without prior opportunity for hearing, whenever it is determined that the public health, interest, or safety so requires, or when the order is responding to a violation involving willfulness. Otherwise, a prior opportunity for a hearing on the order is afforded. For cases in which the NRC believes a basis could reasonably exist for not taking the action as proposed, the licensee will ordinarily be afforded an opportunity to show cause why the order should not be issued in the proposed manner.

D. Escalation of Enforcement Sanctions

NRC considers violations of Severity Levels I, II, or III to be serious. If serious violations occur, NRC will, where necessary, issue orders in conjunction with civil penalties to achieve immediate corrective actions and to deter further recurrence of serious violations. NRC carefully considers the circumstances of each case in selecting and applying the sanction(s) appropriate to the case in accordance with the criteria described in Sections V.B and V.C, above.

Examples of enforcement actions that could be taken for similar Severity Level I, II, or III violations are set forth in Table 2. The actual progression to be used in a particular case will depend on the circumstances. However, enforcement sanctions will normally escalate for recurring similar violations.

Normally the progression of enforcement actions for similar violations will be based on violations under a single license. When more than one facility is covered by a single license, the normal progression will be based on similar violations at an individual facility and not on similar violations under the same license. However, it should be noted that under some circumstances, e.g., where there is common control over some facet of facility operations, similar violations may be charged even though the second violation occurred at a different facility or under a different license. For example, a physical security violation at Unit 2 of a dual unit plant that repeats an earlier violation at Unit 1 might be considered similar.

Table 2.—Examples of Progression of Escalated Enforcement Actions for Similar Violations in the Same Activity Area Under the Same License

Severity of violation	Number of similar violations from the date of the last inspection or within the previous two years (whichever period is greater)		
	1st	2nd	3rd
I	a+d	a+b+c	d.
II	a	a+b	a+b+c.
III		a	a+b.

a. Civil penalty.
b. Suspension of affected operations until the Office Director is satisfied that there is reasonable assurance that the licensee can operate in compliance with the applicable requirements; or modification of the license, as appropriate.
c. Show cause for modification or revocation of the license, as appropriate.
d. Further action, as appropriate.

E. Related Administrative Actions

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In addition to the formal enforcement mechanisms of notices of violation, civil penalties, and orders, NRC also uses administrative mechanisms, such as bulletins, circulars, information notices, generic letters, notices of deviation, and confirmatory action letters to supplement its enforcement program. NRC expects licensees to adhere to any obligations and commitments resulting from these processes and will not hesitate to issue appropriate orders to make sure that such commitments are met.

(1) Bulletins, Circulars, Information Notices and Generic Letters are written notifications to groups of licensees identifying specific problems and recommending specific actions.

(2) Notices of Deviation are written notices describing a licensee's or a vendor's failure to satisfy a commitment where the commitment involved has not been made a legally binding requirement. A notice of deviation requests a licensee or vendor to provide a written explanation or statement describing corrective steps taken (or planned), the results achieved, and the date when corrective action will be completed.

(3) Confirmatory Action Letters are letters confirming a licensee's agreement to take certain actions to remove significant concerns about health and safety, safeguards, or the environment.

F. Referrals to Department of Justice

Alleged or suspected criminal violations of the Atomic Energy Act (and of other relevant Federal laws) are referred to the Department of Justice for investigation. Referral to the Department of Justice does not preclude the NRC from taking other enforcement action under this General Statement of Policy. However, such actions will be coordinated with the Department of Justice to the extent practicable.

VI. Public Disclosure of Enforcement Actions

In accordance with 10 CFR 2.790, all enforcement actions and licensees' responses are publicly available for inspection. In addition, press releases are generally issued for civil penalties and orders. In the case of orders and civil penalties related to violations at Severity Levels I, II, or III, press releases are issued at the time of the order or the proposed imposition of the civil penalty. Press releases are not normally issued for Notices of Violation.

VII. Responsibilities

The Director, Office of Inspection and Enforcement, as the principal enforcement officer of the NRC, has been delegated the authority to issue notices of violations, civil penalties, and orders.[6] Regional Administrators may also issue notices of violation for Severity Levels IV and V violations and may sign notices of violation for Severity Level III violations with no proposed civil penalty and proposed civil penalty actions with the concurrence of the Director, IE. In recognition that the regulation of nuclear activities in many cases does not lend itself to a mechanistic treatment, the Director, IE or the Regional Administrator must exercise judgment and discretion in determining the severity levels of the violations and the appropriate enforcement sanctions, including the decision to impose a civil penalty and the amount of such penalty, after considering the general principles of this statement of policy and the technical significance of the violations and the surrounding circumstances.

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The Commission will be provided written notification of all enforcement actions involving civil penalties or orders. The Commission will be consulted prior to taking enforcement action in the following situations (unless the urgency of the situation dictates immediate action):

(1) An action affecting a licensee's operation that requires balancing the public health and safety or common defense and security implications of not operating with the potential radiological or other hazards associated with continued operation.

(2) Proposals to impose civil penalties in amounts greater than 3 times the Severity Level I values shown in Table 1A;

(3) Any proposed enforcement action that involves a Severity Level I violation;

(4) Any enforcement action that involves a finding of a material false statement;

(5) Any action the Office Director believes warrants Commission involvement; or

(6) Any proposed enforcement action on which the Commission asks to be consulted.

Supplement I—Severity Categories

Reactor Operations

A. Severity I—Violations involving for example:

1. A Safety Limit, as defined in 10 CFR 50.36 and the Technical Specifications, being exceeded;

2. A system[6] designed to prevent or mitigate a serious safety event not being able to perform its intended safety function[7] when actually called upon to work;

3. An accidental criticality; or

4. Release of radioactivity offsite greater than ten (10) times the Technical Specifications limit.[8]

B. Severity II—Violations involving for example:

1. A system designed to prevent or mitigate serious safety events not being able to perform its intended safety function; or

2. Release of radioactivity offsite greater than five (5) times the Technical Specifications limit.

C. Severity III—Violations involving for example:

1. A significant violation of a Technical Specification Limiting Condition for Operation where the appropriate Action Statement was not satisfied within the time allotted by the Action Statement, such as:

a. In a pressurized water reactor, in the applicable modes, having one high-pressure safety injection pump inoperable for a period in excess of that allowed by the action statement; or

b. In a boiling water reactor, one primary containment isolation valve inoperable for a period in excess of that allowed by the action statement.

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2. A system designed to prevent or mitigate a serious safety event not being able to perform its intended function under certain conditions (e.g., safety system not operable unless offsite power is available; materials or components not environmentally qualified);

3. Dereliction of duty on the part of personnel involved in licensed activities;

4. Changes in reactor parameters which cause unanticipated reductions in margins of safety;

5. Release of radioactivity offsite greater than the Technical Specifications limit; or

6. Failure to meet the requirements of 10 CFR 50.59 such that a required license amendment was not sought.

D. Severity IV—Violations involving for example:

1. A less significant violation of a Technical Specification Limiting Condition for Operation where the appropriate Action Statement was not satisfied within the time allotted by the Action Statement, such as:

a. In a pressurized water reactor, a 5% deficiency in the required volume of the condensate storage tank; or

b. In a boiling water reactor, one subsystem of the two independent MSIV leakage control subsystems inoperable.

2. Failure to meet the requirements of 10 CFR 50.59 that does not result in a Severity Level I, II, or III violation;

3. Failure to meet regulatory requirements that have more than minor safety or environmental significance; or

4. Failure to make a required Licensee Event Report.

E. Severity Level V—Violations that have minor safety or environmental significance.

Supplement II—Severity Categories

Part 50—Facility Construction

A. Severity I—Violations involving a structure or system that is completed[9] in such a manner that it would not have satisfied its intented safety related purpose.

B. Severity II—Violations involving for example:

1. A breakdown in the quality assurance program as exemplified by deficiencies in construction QA related to more than one work activity (e.g., structural, piping, electrical, foundations). Such deficiencies normally involve the licensee's failure to conduct adequate audits or to take prompt corrective action on the basis of such audits and normally involve multiple examples of deficient constuction or construction of unknown quality due to inadequate program implementation; or

2. A structure or system that is completed in such a manner that it could have an adverse effect on the safety of operations.

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C. Severity III—Violations involving for example:

1. A deficiency in a licensee quality assurance program for construction related to a single work activity (e.g., structural, piping, electrical or foundations). Such significant deficiency normally involves the licensee's failure to conduct adequate audits or to take prompt corrective action on the basis of such audits, and normally involves multiple examples of deficient construction or construction of unknown quality due to inadequate program implementation;

2. Failure to confirm the design safety requirements of a structure or system as a result of inadequate preoperational test program implementation; or

3. Failure to make a required 10 CFR 50.55(e) report.

D. Severity IV—Violations involving failure to meet regulatory requirements including one or more Quality Assurance Criteria not amounting to Severity Level I, II, or III violations that have more than minor safety or environmental signficance.

E. Severity V—Violations that have minor safety or environmental significance.

Supplement III—Severity Categories

Safeguards

A. Severity I—Violations involving for example:

1. An act of radiological sabotage or actual theft, loss, or diversion of a formula quantity of strategic special nuclear material[10] (SSNM);

2. Actual entry of an unauthorized individual into a vital area or material access area from outside the protected area (i.e., penetration of both barriers) that was not

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[6] The Directors of the Offices of Nuclear Reactor Regulation and Nuclear Material Safety and Safeguards have also been delegated similar authority, but it is expected that normal use of this authority by NRR and NMSS will be confined to actions necessary in the interest of public health and safety. The Director, Office of Administration, has been delegated the authority to issue orders where licensees violate Commission regulations by nonpayment of license fees. It is planned to consider redelegation of some or all of these authorities to the Administrators of the NRC Regional Offices over the next several years.

[6] "System" as used in these supplements, includes administrative and managerial control systems, as well as physical systems.

[7] "Intended safety function" means the total safety function, and is not directed toward a loss of redundancy. For example, considering a BWR's high pressure ECCS capability, the violation must result in complete invalidation of both HPCI and ADS subsystems. A loss of one subsystem does not defeat the intended safety function as long as the other subsystem is operable.

[8] The Technical Specification limit as used in this Supplement (Items A.4, B.2 and C.5) does not apply to the instantaneous release limit.

[9] "Completed" means completion of construction including review and acceptance by the construction QA organization.

[10] See 10 CFR 73.2(bb).

detected at the time of entry; or

3. Failure to promptly report knowledge of an actual or attempted theft or diversion of SSNM or an act of radiological sabotage.

B. Severity II—Violations involving for example:

1. Actual theft, loss or diversion of special nuclear material (SNM) of moderate strategic significance;[11]

2. Failure to control access such that all three elements of access control (barrier, monitoring, and response) at the protected area or vital area are inadequate or two of three elements are inadequate in both the protected and vital area;

3. Failure to implement approved compensatory measures when the central and secondary alarm stations are inoperable;

4. Failure to establish or maintain safeguards systems designed or used to prevent or detect the unauthorized removal of a formula quantity of SNM from areas of authorized use or storage; or

5. Failure to use established transportation security systems designed or used to prevent the theft, loss, or diversion of a formula quantity of SNM or acts of radiological sabotage.

C. Severity III—Violations involving for example:

1. Failure to control access such that two of the three elements of access control at the vital area or protected area barrier are inadequate;

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2. Failure to control access to a transport vehicle or the SNM being transported that does not constitute a Severity I or II violation;

3. Failure to establish or maintain safeguards systems designed or used to prevent or detect the unauthorized removal of SNM of moderate strategic significance from areas of authorized use or storage;

4. Failure to implement approved compensatory measures when the central (or secondary) alarm station is inoperable;

5. Failure to conduct a proper search at the access control point that results in introduction to the site of firearms, explosives, incendiary devices, or other items which could be used for industrial sabotage; or

6. Failure to properly secure or protect classified or other sensitive safeguards information which would significantly assist an individual in an act of radiological sabotage or theft of special nuclear material.

D. Severity IV—Violations involving for example:

1. Failure to establish or maintain safeguards systems designed or used to prevent or detect the unauthorized removal of SNM of low strategic significance[12] from areas of authorized use or storage;

2. Failure to implement 10 CFR Parts 25 and 95 and information addressed under Section 142 of the Act, and the NRC approved security plan relevant to those parts;

3. Failure to control access to a vital area or material access area from inside the protected area or failure to control access to the protected area in that one of the three elements of access control is inadequate;

4. Failure to properly secure or protect classified or other sensitive safeguards information which would not significantly assist an individual in an act of radiological sabotage or theft of special nuclear material; or

5. Other violations, such as failure to follow an approved security plan, that have more than minor safeguards significance.

E. Severity V—Violations that have minor safeguards significance.

Supplement IV—Severity Categories

Health Physics 10 CFR Part 20[13]

A. Severity I—Violations involving for example:

1. Single exposure of a worker in excess of 25 rems of radiation to the whole body, 150 rems to the skin of the whole body, or 375 rems to the feet, ankles, hands, or forearms;

2. Annual whole body exposure of a member of the public in excess of 2.5 rems of radiation;

3. Release of radioactive material to an unrestricted area in excess of ten times the limits of 10 CFR 20.106;

4. Disposal of licensed material in quantities or concentrations in excess of ten times the limits of 10 CFR 20.303; or

5. Exposure of a worker in restricted areas of ten times the limits of 10 CFR 20.103.

B. Severity II—Violations involving for example:

1. Single exposure of a worker in excess of 5 rems of radiation to the whole body, 30 rems to the skin of the whole body, or 75 rems to the feet, ankles, hands or forearms;

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2. Annual whole body exposure of a member of the public in excess of 0.5 rems of radiation;

3. Release of radioactive material to an unrestricted area in excess of five times the limits of 10 CFR 20.106;

4. Failure to make an immediate notification as required by 10 CFR 20.403(a)(1) and 10 CFR 20.403(a)(2);

5. Disposal of licensed material in quantities or concentrations in excess of five times the limits of 10 CFR 20.303; or

6. Exposure of a worker in restricted areas in excess of five times the limits of 10 CFR 20.103.

C. Severity III—Violations involving for example:

1. Single exposure of a worker in excess of 3 rems of radiation to the whole body, 7.5 rems to the skin of the whole body, or 18.75 rems to the feet, ankles, hands or forearms;

2. A radiation level in an unrestricted area such that an individual could receive greater than 100 millirem in a one hour period or 500 millirem in any seven consecutive days;

3. Failure to make a 24-hour notification as required by 10 CFR 20.403(b) or an immediate notification required by 10 CFR 20.402(a);

4. Substantial potential for an exposure or release in excess of 10 CFR 20 whether or not such exposure or release occurs (e.g., entry into high radiation areas, such as under reactor vessels or in the vicinity of exposed radiographic sources, without having performed an adequate survey, operation of a radiation facility with a nonfunctioning interlock system);

5. Release of radioactive material to an unrestricted area in excess of the limits of 10 CFR 20.106;

6. Improper disposal of licensed material not covered in Severity Levels I or II;

7. Exposure of a worker in restricted areas in excess of the limits of 10 CFR 20.103;

8. Release for unrestricted use of contaminated or radioactive material or equipment which poses a realistic potential for significant exposure to members of the public, or which reflects a programmatic (rather than isolated) weakness in the radiation control program;

9. Cumulative worker exposure above regulatory limits when such cumulative exposure reflects a programmatic, rather than an isolated weakness in radiation protection;

10. Conduct of licensee activities by a technically unqualified person; or

11. Significant failure to control licensed material.

D. Severity IV—Violations involving for example:

1. Exposures in excess of the limits of 10 CFR 20.101 not constituting Severity Level I, II, or III violations;

2. A radiation level in an unrestricted area such that an individual could receive greater than 2 millirem in a one hour period or 100 millirem in any seven consecutive days;

3. Failure to make a 30-day notification required by 10 CFR 20.405;

4. Failure to make a followup written report as required by 10 CFR 20.402(b), 20.408, and 20.409; or

5. Any other matter that has more than minor safety or environmental significance.

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E. Severity V—Violations that have minor safety or environmental significance.

Supplement V—Severity Categories

Transportation[14]

A. Severity I—Violations of NRC transportation requirements involving for example:

1. Annual whole body radiation exposure of a member of the public in excess of 0.5 rems of radiation; or

2. Breach of package integrity resulting in surface contamination or external radiation levels in excess of ten times the NRC limits.

B. Severity II—Violations of NRC transportation requirements involving for example:

1. Breach of package integrity resulting in surface contamination or external radiation levels in excess of NRC requirements;

2. Surface contamination or external radiation levels in excess of five times NRC limits that did not result from a breach of package integrity; or

3. Failure to make required initial notifications associated with Severity Level I or II violations.

C. Severity III—Violations of NRC transportation requirements involving for example:

1. Breach of package integrity;

2. Surface contamination or external radiation levels in excess of, but less than a

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[11] See 10 CFR 73.2(x).

[12] See 10 CFR 73.2(y).

[13] Personal over exposures and associated violations, incurred during a life saving effort, will be treated on a case-by-case basis.

[14] Some transportation requirements are applied to more than one licensee involved in the same activity such as a shipper (10 CFR 73.20) and a carrier (10 CFR 70.20a). When a violation of such a requirement occurs, enforcement action will be directed against the responsible licensee which, under the circumstances of the case, may be one or more of the licensees involved.

factor of five above NRC requirements, that did not result from a breach of package integrity;

3. Any noncompliance with labelling, placarding, shipping paper, packaging, loading, or other requirements that could reasonably result in the following:

a. Improper identification of the type, quantity, or form of material;

b. Failure of the carrier or recipient to exercise adequate controls; or

c. Substantial potential for personnel exposure or contamination, or improper transfer of material; or

4. Failure to make required initial notification associated with Severity Level III violations.

D. Severity IV—Violations of NRC transportation requirements involving for example:

1. Package selection or preparation requirements which do not result in a breach of package integrity or surface contamination or external radiation levels in excess of NRC requirements; or

2. Other violations that have more than minor safety or environmental significance.

E. Severity V—Violations that have minor safety or environmental significance.

Supplement VI—Severity Categories

Fuel Cycle and Materials Operations

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A. Severity I—Violations involving for example:

1. Radiation levels, contamination levels, or releases that exceed ten times the limts specified in the license;

2. A system designed to prevent or mitigate a serious safety event not being operable when actually required to perform its design function; or

3. A nuclear criticality accident.

B. Severity II—Violations involving for example:

1. Radiation levels, contamination levels, or releases that exceed five times the limits specified in the license; or

2. A system designed to prevent or mitigate a serious safety event being inoperable.

C. Severity III—Violations involving for example:

1. Failure to control access to licensed materials for radiation purposes as specified by NRC requirements;

2. Possession or use of unauthorized equipment or materials in the conduct of licensee activities which degrades safety:

3. Use of radioactive material on humans where such use is not authorized;

4. Conduct of licensed activities by a technically unqualified person;

5. Radiation levels, contamination levels, or releases that exceed the limits specified in the license; or

6. Medical therapeutic misadministrations.

D. Severity IV—Violations involving for example:

1. Failure to maintain patients hospitalized who have cobalt-60, cesium-137, or iridium-192 implants or to conduct required leakage or contamination tests, or to use properly calibrated equipment;

2. Other violations that have more than minor safety or environmental significance; or

3. Failure to report medical diagnostic misadministrations.

E. Severity V—Violations that have minor safety or environmental significance.

Supplement VII—Severity Categories

Miscellaneous Matters

A. Severity I—Violations involving for example:

1. A Material False Statement (MFS) [15] in which the statement made was deliberately false;

2. Falsification of records which NRC requires be kept of significant information in which the records were deliberately falsified by or with the knowledge of management;

3. A knowing and intentional failure to provide the notice required by Part 21: or

4. Action by senior corporate management in violation of Section 210 of the ERA against an employee.

B. Severity II—Violations involving for example:

1. A MFS or a reporting failure, involving information which, had it been available to the NRC and accurate at the time the information should have been submitted, would have resulted in regulatory action or would likely have resulted in NRC seeking further information;

2. A MFS in which the false statement was made with careless disregard;

3. Deliberate falsification of records which NRC requires be kept involving significant information;

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4. Action by plant management above first-line supervision in violation of section 210 of the ERA against an employee; or

5. A failure to provide the notice required by Part 21.

C. Severity III—Violations involving for example:

1. A MFS not amounting to a Severity Level I or II violation.

2. Deliberate falsification, or falsification by or with the knowledge of management, of records which the NRC requires be kept that did not involve significant information.

3. Action by first-line supervision in violation of section 210 of the ERA against an employee; or

4. Inadequate review or failure to review such that, if an appropriate review had been made as required, a Part 21 report would have been made.

D. Severity IV—Violations involving for example:

1. Inadequate review or failure to review under Part 21 or other procedural violations associated with Part 21 with more than minor safety significance;

2. A false statement caused by an inadvertent clerical or similar error involving information which, had it been available to NRC and accurate at the time the information should have been submitted, would probably not have resulted in regulatory action or NRC seeking additional information; or

E. Severity V—Violations of minor procedural requirements of Part 21.

Supplement VIII—Severity Categories

Emergency Preparedness

A. Severity I—Violations involving for example:

In a general emergency, licensee failure to promptly: (1) correctly classify the event, (2) make required notifications to responsible Federal, State, and local agencies, or (3) respond to the event (e.g., assess actual or potential offsite consequences, activate emergency response facilities, and augment shift staff).

B. Severity II—Violations involving for example:

1. In a site area emergency, licensee failure to promptly: (1) correctly classify the event, (2) make required notifications to responsible Federal, State, and local agencies, or (3) respond to the event (e.g., assess actual or potential offsite consequences, activate emergency response facilities, and augment shift staff); or

2. Licensee failure to meet or implement more than one emergency planning standard involving assessment or notification.

C. Severity III—Violations involving for example:

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1. In an alert, licensee failure to promptly: (1) correctly classify the event, (2) make required notifications to responsible Federal, State, and local agencies, or (3) respond to the event (e.g., assess actual or potential offsite consequences, activate emergency response facilities, and augment shift staff); or

2. Licensee failure to meet or implement one emergency planning standard involving assessment or notification.

D. Severity IV—Violations involving for example: Licensee failure to meet or implement any emergency planning standard or requirement not directly related to assessment and notification.

E. Severity V—Violations that have minor safety or environmental significance.

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[15] In essence, a Material False Statement is a statement that is false by omission or commission and is relevant to the regulatory process. As can be seen in the examples, in determining the specific severity level of a violation involving material false statements or falsification of records, consideration will be given to such factors as the position of the person involved in the violation (e.g., first line supervisor or senior manager), the significance of the information involved, and the intent of the violator (i.e., negligence not amounting to careless disregard, careless disregard, or deliberateness). The relative weight given to each of these factors in arriving at the appropriate severity level will be dependent on the circumstances of the violation.

PART 2

RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS

PROPOSED RULE MAKING

44 FR 12428
Published 3/7/79
Comment period expires 4/23/79

[10 CFR Part 2]

RULES OF PRACTICE

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Commission is amending its rule dealing with *ex parte* communications and the separation of adjudicatory and non-adjudicatory functions so that those rules will accord with the Government in the Sunshine Act, Pub. L. No. 94-409. The substance of the proposed rules is largely unchanged from the Commission's current rules and practices in the areas involved.

DATE: Comments must be received on or before April 23, 1979.

ADDRESSES: Written comments should be submitted to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, ATTN: Docketing and Service Branch. Copies of all comments received may be examined in the Commission's Public Document Room at 1717 H Street, N.W., Washington, D.C.

FOR FURTHER INFORMATION CONTACT:

Stephen S. Ostrach, Esq., Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, (202) 634-3224.

SUPPLEMENTARY INFORMATION: These proposed amendments have two primary purposes. They are designed to adapt the Commission's rules to the terminology of the Government in the Sunshine Act and they are also designed to codify the practices the Commission now employs in its adjudicatory proceedings with regard to *ex parte* communications.

Both the separation of functions regulation, § 2.719, and the *ex parte* regulation, § 2.780, are based on the concept of "Commission adjudicatory employees." This term is new, but the principle it represents is embodied in the present regulations. It is intended to include all of those employees who participate in the making of the Commission's (or the subordinate adjudicatory panels') decisions in adjudicatory proceedings, and it should be broadly construed. Of course, it does not include those people whose participation in the decisionmaking process is limited to appearance as witnesses or counsel.

The Commission has requested the General Counsel's office to examine the extent to which direct communications between the Commissioners and the Commission staff may legally and practically be employed as management tools. In particular, the study will examine the extent to which Commissioners can, not on the record, communicate with staff on issues which arise in specific proceeding in adjudication without violating the *ex parte* provisions of the Administrative Procedure Act and without violating the "hearing" requirement of the Atomic Energy Act. This study, which is now scheduled to be completed in approximately two months, may lead to recommendations for modification of the regulations proposed below or for other modifications in the Commission's current regulations and practices. Public comment on the issue of such communications may be made now or may be made after the General Counsel's recommendations are made public.

Proposed § 2.719 is drawn from 5 U.S.C. 554(d) and the Commission's present regulation on separation of functions. Subsection (b) is designed to prevent adjudicatory employees from being subordinate to non-adjudicatory employees so that no situations can arise in which the independence of the Commission's adjudications may be suspect. Subsection (c) will prevent Commission staff personnel who have appeared as parties in adjudications from participating in making the decisions in those or factualy related adjudications. This provision does not apply to uncontested applications for initial licenses or to informal rulemakings conducted pursuant to 5 U.S.C. 553.

Section 2.780 is intended to cover all Commission adjudications. It does not apply to informal rulemakings or to decisions on requests for enforcement action pursuant to 10 CFR 2.206. It does apply once an enforcement proceeding has been instituted pursuant to 10 CFR 2.202. There are several specific exclusions from the definition of *ex parte* communication in subsection 2.780(b). The first exception involves requests for reports on the current status of a proceeding or upon scheduling matters. This exception permits the parties to obtain easily this necessary and routine information. The second exception is for *ex parte* communications which are specifically permitted by statute or regulation, such as requests for subpoenas or discussions of certain classified information (see 10 CFR 2.912). This exception simply recognizes that the policy against *ex parte* communications can be overcome by other policy considerations. Aslo excluded from the definition are communications by or to members of the Office of the General Counsel regarding matters pending before a court or another agency. Although in most cases issues are litigated in the courts only after they have been adjudicated by the Commission, there have been cases in which matters were pending in litigation at the same time that those or related issues were before the Commission or the Boards. In such cases it is sometimes necessary for members of the Office of the General Counsel to discuss the litigation with the parties who may also be parties to the Commission proceeding. Subsection 2.780(b)(3) recognizes this need and excludes such communications from the definition of *ex parte* communications so long as they are limited to discussions of the matters pending before the court (or other agency). The fourth exemption permits adjudicatory employees to communicate directly with the staff in uncontested licensing proceedings which, as defined by 10 CFR 2.4(n), are proceedings in which the only parties are the staff and the applicant and where there are no issues in dispute. This provision is carried over from 10 CFR 2.780(e) as it is presently written. The absence of any dispute involving the application ensures that this provision will not prejudice any party.

The final exclusion from the definition of *ex parte* communications involves generic issues. This exclusion takes account of the Commission's dual responsibilities as both an adjudicatory and a rulemaking body. The Commission often has before it generic rulemaking proposals which would alter Commission policy in broad areas of its responsibilities. In many cases such proposals, if adopted, would have an effect on adjudicatory proceedings and, in some cases, on matters currently in issue in such adjudications. To include these generic matters within the definition of *ex parte* communications would significantly impair the Commission's ability to resolve generic issues through rulemaking. Since the same generic issue may affect many adjudications, each with separate parties, resolution of these issues through adjudicatory or quasi-adjudicatory procedures might in some cases prevent the Commission from taking needed regulatory action in an expeditious fashion. The Commission believes that this policy accords with law and is justified for the policy reasons given above. However, the Commission recognizes that this provision cannot be used as a means of circumventing the adjudicatory process and will act to ensure that its use is limited to matters that are of generic rather than limited concern.

Subsections (c) and (d) of § 2.780 are the essential operative provisions of the *ex parte* rule. Together they bar *ex parte* communications either to or from Commission adjudicatory employees. The prohibitions apply to "interested persons" as that term is used in the Government in the Sunshine Act. The long-standing Commission policy against *ex parte* communications between adjudicatory and non-adjudicatory employees is also made explicit. Subsection (e) is a codification of current procedures for dealing with *ex parte* communications. It provides that, to the extent possible, *ex parte* communications will be channeled to the Office of the Executive Director for Operations for handling by that office. Since the communications will not reach any adjudicatory employee, this means they will in most cases not have to be copied and circulated to the parties. This will result in a significant cost savings to the Commission which presently copies and circulates all *ex parte* communications regardless of the volume of such communications or whether they reached the Commission employee to whom they were sent. Subsections (f) and (g) provide how *ex parte* communications which are received or made by adjudicatory employees will be treated. They are modeled after the provisions of the Sunshine Act, and also provide that, in most cases, the Secretary of the Commission will send copies of the communication to all parties to the proceeding.

Subsection (h) explains how proceedings to impose sanctions for violations of the *ex parte* rule shall be commenced. The Commission expects that the sanctions imposed in any case will take into account the intent of the persons involved, the seriousness of the violation, the nature of the issues and their importance to the proceeding, the interests of other parties or persons, the public interest and other relevant factors. Subsection (i) defines when the prohibition against *ex parte* communications comes into effect. Subsection (j)(1) defines the term proceeding so as to exclude export and import proceedings from the definition, since those proceedings are separately treated in Part 110 of the Commission's regulations. Furthermore, consistent with current Commission policy, rulemaking proceedings conducted pursuant to Subpart H of 10 CFR Part 2 are also not included within the coverage of the *ex parte* prohibition except as the Commission may otherwise direct in particular rulemakings. Subsection (j)(2) defines the term "interested person" as that term is defined in the legislative history of the Sunshine Act. H.R. Rep. 94-880 Part I, 94th Cong. 2nd Sess. at 19-20 (1976).

Pursuant to section 161 of the Atomic Energy Act and 5 U.S.C. 553, notice is hereby given that adoption of the following amendments to 10 CFR Part 2 is contemplated. All interested persons who desire to submit written comments or suggestions for consideration in connection with the proposed amendments should send them to the Secretary, United States Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch. All comments must be received by April 23, 1979. Copies of all comments received may be examined in the Commission's Public Document Room at 1717 H Street NW., Washington, D.C.

1. It is proposed to amend § 2.719 to read as follows:

§ 2.719 Separation of Functions: Commission Adjudicatory Employees.

(a) As defined in this section, Commission adjudicatory employees include:

(1) The Chairman and Commissioners and members of their personal staffs;

(2) Members of the Atomic Safety and Licensing Appeal Panel and members of the staff of that panel;

(3) Members of the Atomic Safety and Licensing Board Panel and members of the staff of that panel;

(4) The General Counsel and employees of the Office of the General Counsel;

(5) The Director of the Office of Policy Evaluation and employees of that office;

(6) The Secretary and employees of the Office of the Secretary; and

(7) The Director of the Office of Inspector and Auditor and employees of that office.

(b) Commission adjudicatory employees shall perform no duties inconsistent with their adjudicatory responsibilities. In carrying out their adjudicatory responsibilities these employees will not be responsible to or subject to the supervision or direction of any Commission officer or employee except another Commission adjudicatory employee acting under this Subpart.

(c) Except as provided in § 2.780 of this Subpart and except in uncontested proceedings involving an application for initial licensing, no officer or employee of the Commission except a member of the Commission who has engaged in the performance of any investigative or prosecuting functions in that case or in any factually related case may participate or advise in the initial or final decision, except as a witness or counsel in the proceeding. Representation of the Commission in any court of law or before any agency other than the Commission does not constitute the performance of investigative or prosecuting functions for the purposes of this section.

2. It is proposed to amend § 2.780 to read as follows:

§ 2.780 Ex parte communications: Commission adjudicatory employees.

(a) As defined in this section, Commission adjudicatory employees include:

(1) The Chairman and Commissioners and members of their personal staffs;

(2) Members of the Atomic Safety and Licensing Appeal Panel and members of the staff of that panel;

(3) Members of the Atomic Safety and Licensing Board Panel and members of the staff of that panel;

(4) The General Counsel and employees of the Office of the General Counsel;

(5) The Director of the Office of Policy Evaluation and employees of that office;

(6) The Secretary and employees of the Office of the Secretary; and

(7) The Director of the Office of Inspector and Auditor and employees of that office.

(b) As used in this section, the term *ex parte* communication means an oral or written communication relevant to the merits of any proceeding on the record pending before the NRC which is not made on the public record and with respect to which reasonable prior notice to all participants in the proceeding is not given, but it shall not include:

(1) Requests for status reports;

(2) *Ex parte* communications specifically permitted by statute or regulation (for example, § 2.720 of this part);

(3) Communications made to or by members of the Office of the General Counsel regarding matters pending before a court or another agency;

(4) Communications between staff and any Commission adjudicatory employee in a proceeding involving an application for initial licensing other than in a contested proceeding as defined by § 2.4(n) of this Part; and

(5) Communications between the Commission and staff regarding generic issues involving public health and safety or other statutory responsibilities of the Commission not specifically related to any particular proceeding pending before the Commission.

(c) No Commission adjudicatory employee will make or knowingly cause to be made to any interested person outside the NRC or to any NRC employee engaged in the performance of investigative or prosecuting functions in that or in any factually related proceeding an *ex parte* communication.

(d) No interested person outside the NRC and no NRC employee engaged in the performance of investigative or prosecuting functions in that proceeding or any factually related proceeding shall make or shall knowingly cause to be made to any Commission adjudicatory employee an *ex parte* communication.

(e) To the extent possible, all *ex parte* communications directed to any

Commission adjudicatory employee will be referred to the Office of the Executive Director for Operations for handling by that office, and such *ex parte* communications will not be transmitted to the Commission adjudicatory employee to whom they were directed. Such *ex parte* communications shall be placed in a file associated with but separate from the record of the proceeding to which the *ex parte* communication pertains. If a communication was made or solicited by a Commission adjudicatory employee, or if it is otherwise appropriate, the Executive Director for Operations will serve the *ex parte* communication on all parties to the proceeding to which it pertains.

(f) Any Commission adjudicatory employee who, despite paragraph (e) of this section, receives, makes or knowingly causes to be made a communication prohibited by this section will place in a public file associated with but separate from the public record of that proceeding:

(1) All such communications which are written;

(2) Memoranda stating the substance of any such communications which were oral; and

(3) All written responses, and memoranda stating the substance of all oral responses to the materials discussed in paragraphs (f)(1) and (f)(2) of this section.

(g) The Secretary will send copies of any communication of the kinds listed in paragraphs (f)(1), (2) and (3) of this section to all participants to the proceeding with respect to which it was made, and will notify the communicator of the provisions of this regulation prohibiting *ex parte* communications. If the communications are from persons other than participants to the proceedings or their agents, and the Secretary determines that it would be too burdensome to send copies of the communications to all participants because: (1) the communications are so voluminous, or (2) the communications are of such borderline relevance to the issues of the proceeding, or (3) the participants to the proceeding are so numerous, the Secretary may instead notify the participants that the communications have been received, placed in the file, and are available for examination, and will be sent upon request.

(h) Upon receipt of a communication knowingly made or knowingly caused to be made in violation of this section, a Commission adjudicatory employee may, to the extent consistent with the interests of justice and the policy of the underlying statutes, recommend to the appropriate Commission adjudicatory tribunal that the person making or causing the prohibited communication be made to show cause why his claim or interest in the proceeding should not be denied, disregarded, dismissed or otherwise adversely affected because of such violation.

(i) The prohibitions of this section shall apply when a proceeding is first noticed for a formal hearing on the record, unless the person responsible for the communication has knowledge that it will be noticed, in which case the prohibition shall apply at the time he acquires such knowledge.

(j) As used in this section:

(1) The term proceeding shall not refer to any proceeding or proceedings governed by Part 110 of this chapter, and except as the Commission may otherwise direct, shall not refer to any proceeding for the adoption, amendment or repeal of any rule or regulation which is conducted pursuant to Subpart H of this Part, and

(2) The term interested person is intended to be a wide, inclusive term covering any individual or other person with an interest in the agency proceeding that is greater than the general interest the public as a whole may have. The interest need not be monetary, nor need a person be a party to, or intervenor in, the agency proceeding to come under this section. The term includes, but is not limited to, parties, competitors, public officials, and nonprofit or public interest organizations and associations with a special interest in the matter regulated. The term does not include a member of the public at large who makes a casual or general expression of opinion about pending proceedings.

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44 FR 33883
Published 6/13/79
Comment period expires 7/6/79

[10 CFR Part 2]

Study of Nuclear Power Plant Construction During Adjudication; Request for Public Comments

AGENCY: Nuclear Regulatory Commission.

ACTION: Request for comments.

SUMMARY: The Nuclear Regulatory Commission's Advisory Committee on Construction During Adjudication is studying several aspects of the Commission's licensing procedures. The Advisory Committee is seeking the views of the public on the Commission's "immediate effectiveness" rule (10 CFR 2.764). That rule provides that a construction permit can be issued on the basis of an initial decision of an Atomic Safety and Licensing Board even though that decision is subject to further review within the Commission. The Committee believes that the views of the public on the rule would be of help to it in evaluating the rule's operation and impact and in assessing possible changes for improving the licensing procedures.

DATES: Comments must be received by July 6, 1979.

ADDRESS: Send comments to: Secretary of the Commission, Nuclear Regulatory Commission, Washington, D.C. 20555, ATTN: Docketing and Service Branch.

Copies of all comments received may be examined in the Commission's Public Document Room at 1717 H Street, N.W., Washington, D.C. 20555.

FOR FURTHER INFORMATION CONTACT: Stephen S. Ostrach, Office of the General Counsel, Nuclear Regulatory Commission, Washington, D.C. 20555, (202) 634-3224.

SUPPLEMENTARY INFORMATION: The Nuclear Regulatory Commission's Advisory Committee on Construction During Adjudication is seeking the views of the public on the Commission's "immediate effectiveness" rule (10 CFR 2.764). The views of those who have participated in licensing proceedings in which the rule was significant are of particular interest. In addition to general views, the group wishes public comment on a number of specific questions about the rule. Comments must be received by July 6, 1979, and should be submitted to the Secretary of the Commission, Nuclear Regulatory Commission, Washington, D.C. 20555, ATTN: Docketing and Service Branch. Copies of all comments received may be examined in the Commission's Public Document Room at 1717 H Street, N.W., Washington, D.C. 20555. Further information may be obtained from Stephen S. Ostrach, Office of the General Counsel, Nuclear Regulatory Commission, Washington, D.C. 20555, (202) 634-3224.

The Nuclear Regulatory Commission has established an Advisory Committee on Construction During Adjudication. The Committee is studying several aspects of the Commission's licensing procedures including, in particular, the Commission's "immediate effectiveness" rule (10 CFR 2.764). That rule provides that a construction permit can be issued on the basis of an initial decision of an Atomic Safety and Licensing Board even though that decision is subject to further review within the Commission.

The Committee believes that the views of the public on the rule would be of help to it in evaluating the rule's operation and impact and in assessing possible changes for improving the licensing process. The views of those who have actually participated in nuclear licensing proceedings in which the rule played a significant role are of particular interest to the group. The questions given below have been provided principally as an aid to those persons with actual experience in licensing proceedings, but they may be answered by any person. The group desires the views of parties associated with each of the different interests in licensing cases.

If each viewpoint on the rule is presented fully by these comments, the Committee will be able to formulate its recommendations to the Commission with confidence that it has taken into account a fair balance of all viewpoints. The questions concerning which respondents views are desired are as follows:

1. In a general way, how were the proceedings in which you participated affected by the rule permitting construction during agency appellate review? If there had been no such rule during appellate review, how would the proceedings have been different?

2. Was the appellate resolution of any issue which you appealed prejudiced by ongoing construction during the pendency of the appeal?

3. If so, please state the case, issue and elaborate the details, citing specific references (i.e., briefs, decisions, transcripts, etc.) which you believe indicate such prejudice.

4. In these proceedings, how long after the issuance of a limited work authorization or a construction permit did the principal environmental impact of construction occur? How did the timing of this impact affect the proceeding? Should consideration be given to changing the order in which issues are decided (currently NEPA and site suitabilitiy first, safety second)?

5. Was a stay of construction sought pending appeal? Did construction during the pendency of the stay request affect the proceeding? If so, how? Was an evidentiary hearing held on the stay request? Did such hearing (or the lack thereof) affect the disposition of the request?

6. Was interlocutory review (certification or referral) sought during the proceeding? If interlocutory review had been available, would that review have improved the proceeding? Should consideration be given to adopting a standard for interlocutory review which would facilitate an early appellate decision on the inclusion or exclusion of issues in the proceeding?

7. The following are some possible alternatives to the present rules. What effect would these alternatives have had if they had applied to the proceedings in which you participated? Do you believe, based on your experience, that any of these alternatives should be adopted?

a. Delay effectiveness of Licensing Board decisions:

1. By 10 or 15 days, to allow parties to prepare stay motions for the Appeal Board.

2. Until the Appeal Board rules on any stay motion before it.

3. Until the Commission rules on a stay.

4. Until the Appeal Board rules on the merits.

5. Until the Commission rules on the merits.

[This last suboption would in effect *repeal* the immediate effectiveness rule.]

b. Restrict effectiveness to certain cases, in which immediate effectiveness is less likely to create problems. The following are examples:

1. The case is uncontested.

2. The decision is unanimous.

3. Applicant requests immediate effectiveness and no good is shown to delay.

4. Applicant shows urgency and no good cause is shown to delay.

5. The design is an approved standard design.

6. For custom plants, design definition is well along toward final design (meeting design status criteria which would be specified).

7. The case involves a subsequent unit for a site already approved for at least one unit.

8. The site has been reviewed and received final Commission approval.

c. Restrict the amount of work the applicant may do in reliance upon the Licensing Board's decision:

1. Up to some dollar limit on:

—total commitments, or

—site-dependent commitments.

2. To certain kinds of work (e.g., items which require long lead-time, or have low impact).

3. To exclude certain items, either because they would have high or irreparable environmental impact, or because they depend upon resolution of contested issues.

d. Allow initial decisions to become immediately effective only if the authorization or permit has certain conditions attached. For examples:

1. A requirement to restore the site if the favorable Board decision is ultimately reversed.

2. Conditions on the construction sequence or schedule (to limit environmental damage during appellate review and to safeguard against an applicant rushing to build up a sunk-cost case against later reversal).

e. Alter stay standards while leaving the immediate effectiveness rule in place. Following are examples of alternative standards:

1. Alter the burden or proof on stays.

2. Grant a stay when the Appeal Board confirms the existence of an important policy or legal issue appropriate for Commission review.

3. Make stay standards vary according to the issue on which appeal is taken:

(a) Environmental as contrasted with safety issues.

(b) Site-related issues.

f. Change appellate procedures so as to permit the Commission or the Appeal Board to reach certain issues earlier. Following are examples of such changes:

1. Allow interlocutory appeals for issues (such as siting) which require decision.

2. Certify questions more frequently to the Appeal Board and the Commission

3. Establish a mechanism for the Commission to monitor proceedings of lower boards.

4. Expedite decisions on issues affected by construction during adjudication.

8. It would also be helpful to have the public's views on aspects of the immediate effectiveness or stay rules which the above questions may not specifically address. If you are in favor of the present rules as they are now written, please give us your reasons. Also, please discuss any alternatives to or changes in the present immediate effectiveness rule (§ 2.764) or stay criteria (§ 2.788) which you feel may be appropriate.

(next page is 2-PR-6)

45 FR 34279
Published 5/22/80
Comment period expires 7/7/80

Comment period extended to 7/21/80

10 CFR Parts 2, 50

Possible Amendments to "Immediate Effectiveness" Rule

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Proposed rulemaking.

SUMMARY: The Commission is considering amendments to its "immediate effectiveness" rule. That rule provides that construction on a nuclear power plant can begin on the basis of an initial decision by an Atomic Safety and Licensing Board even though that decision is subject to further review within the Commission. The Commission is concerned that the present rules often prevent it from reviewing a case until construction is well underway. The Commission is considering three alternative amendments to that rule, and is also considering retaining the present rule unchanged.

DATES: Comments must be received on or before July 7, 1980.

ADDRESSES: All persons who desire to submit written comments or suggestions for consideration in connection with the proposed amendments should send them to the Secretary, United States Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch. copies of all comments received may be examined in the Commission's Public Document Room at 1717 H Street, NW., Washington, DC. Persons who have commented previously on this subject in connection with the work of the Federal Advisory Committee, mentioned below, may wish to make reference to their previous comments, and to direct their further remarks to the specific features of the three options for change which are now presented.

FOR FURTHER INFORMATION CONTACT: Peter Crane, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, (202) 634-1465.

SUPPLEMENTARY INFORMATION: In its *Seabrook* opinion of January 6, 1978, the Commission announced that it intended to monitor more effectively the proceedings of its lower boards. *Public Service Company of New Hampshire*, 7 NRC 1, 7. It stated that in practice its current rules often prevent it from reviewing a case until construction is well underway and that this might adversely affect either the quality of its decisionmaking process or the public's

perception of that process, or both. It directed that a study be made of the following questions:

1. "The effect which would be achieved by relaxation of our stay standards so that site-related issues in potentially troublesome cases may be taken up before large sums of money are committed and sites irrevocably altered; and

2. Ways in which our appellate administrative procedures may assure earlier resolution of all the issues arising out of a licensing and cut relitigation and piecemeal review to a minimum."

In January of 1979 the Commission established a Federal Advisory Committee to conduct the study; on December 12, 1979 the Advisory Committee submitted its final report (NUREG–06436) to the Commission. Single copies of NUREG–0646 may be obtained without charge by writing to the Director, Division of Technical Information and Document Control, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. The report contained three options for altering the Commission's "immediate effectiveness" rule (10 CFR 2.764) together with a discussion of the advantages and disadvantages of retaining the present licensing system unchanged. It should be noted that the report, and the options which it presented, dealt only with the issue of construction during adjudication, and not with the issue of operation during adjudication. The Commission is now considering whether to retain the present system or to adopt one of several possible options for change.

In January 1980, the Commission's Office of General Counsel completed and presented to the Commission a separate but related study, entitled "The Nuclear Regulatory Commission's Appellate System", (NUREG–0648). The study discussed the history and capabilities of the present appellate system, and the practices of other agencies, analyzed the workload of the Atomic Safety and Licensing Appeal Panel, evaluated options available to the Commission, and presented conclusions, including some recommendations for change of the appellate system. Persons who are interested in the proposed rules set forth below may wish to provide comments in light of the discussions and conclusions in both studies. Copies of that study are available for public inspection in the Commission's Public Document Rooms. Single copies of the appellate study (NUREG–0648) may be obtained by written request addressed to the Director, Division of Technical Information and Document Control, Nuclear Regulatory Commission, Washington, D.C. 20555. Notice of the availability of NUREG–0648 was published in the **Federal Register** on January 30, 1980 (45 FR 6873). The notice solicited public comment on NUREG–0648, to be forwarded to the Commission by March 17, 1980.

Summary of the Present Licensing System

To construct a nuclear power plant an applicant must file with the Commission a detailed application addressing both the design of the proposed facility and its potential environmental impacts. Once that application has been thoroughly reviewed by the Commission staff, an adjudicatory hearing is held on the application before an Atomic Safety and Licensing Board. Full adjudicatory procedures, including the right to present and cross-examine witnesses, are available in the hearing and, in addition to NRC staff and the applicant, any persons whose interests may be affected by the proposed plant may participate as parties. The Licensing Board's decision must be based solely on the record compiled before it. If the Board finds reasonable assurance that the plant as designed will not be inimical to the health and safety of the public, and that the overall cost-benefit balance mandated by the National Environmental Policy Act (NEPA) favors granting the application, it will authorize a construction permit. The permit will be effective immediately unless a party has shown the Board good cause why it should not be. 10 CFR 2.764 provides that the NRC staff must issue the permit within 10 days after the Board's decision, construction may then begin.

There are two avenues available to a party who objects to the Board's initial decision. The primary mechanism is appellate review. All Licensing Board decisions, whether or not appealed, are reviewed on the merits by a three-member Atomic Safety and Licensing Appeal Board which has full authority to review the legal and factual conclusions reached by the Licensing Board. The Appeal Board's decision in turn is subject to discretionary review by the Commission itself, either on its own motion or by the granting of a petition for review (a "certiorari petition") filed by a party pursuant to 10 CFR 2.786. Finally, any party can seek judicial review of a final Commission order in one of the United States Courts of Appeals.

In addition, a party appealing a licensing board decision may seek a stay. The immediate effectiveness rule normally permits construction to proceed during this entire appelate review. The Commission recognized, however, the need for a procedure which would allow a party to seek relief from a decision while that decision was on appeal. Rules were therefore adopted which provide that a stay may be sought, first from the Appeal Board, and if the Board denies the request, then from the Commission. The criteria used to rule on the stay request were taken from those used by courts to judge requests for stay of administrative decisions. The criteria are commonly referred to as the *Virginia Petroleum Jobbers* criteria, after the case in which they were first articulated, *Virginia Petroleum Jobbers Ass'n* v. *FPC*, 259 F.2d 921 (D.C. Cir. 1958).

Options for changing the present licensing system

The three options which are being considered for changing the present system are as follows:

Option A—Effectiveness as an Additional Issue in Licensing

This option would require the Licensing Board to make a separate ruling on the question whether its initial decision should be immediately effective. The ruling would be based upon the record, and would deny effectiveness if the Board found, at close of hearing, any substantial question on an issue which could be affected by the early stages of construction at the site. Such issues would include, for example, alternative sites, site suitability, and the overall NEPA cost-benefit balance; no issue would necessarily be excluded. The merits of any substantial question on these issues would have to be resolved on appeal before construction at the site could begin. A "substantial question," for these purposes, does not require the Board to find that its own ruling may be incorrect, but rather that the party which did not prevail on the issue has demonstrated substantial, non-frivolous arguments which could be raised on appeal.

In a sense, Option A may be seen as the functional equivalent of retaining the present system of immediate effectiveness, but with liberalized stay standards in place of the strict *Virginia Petroleum Jobbers* standard. Alternatively, the Commission could simply alter its present stay standards to provide that a stay will be granted if a party demonstrates that there is a substantial question as to the correctness of the resolution of an issue which might be prejudiced by construction. (This is the approach taken in Option D.) Option A achieves approximately the same effect, except that in the case of a stay, the burden would be on the proponent of the stay to overcome the presumption in favor of immediate effectiveness; under Option

A. however. there would be no presumption for or against immediate effectiveness. As a practical matter. this might be significant only in uncontested cases. where under Option A. effectiveness might be deferred if the Licensing Board found that there was substantial question as to the correctness of its own resolution of a particular issue which might be prejudiced by construction.

Chronologically. Option A would operate as follows:

A. At the hearing:

1. Applicant would advise the Board and parties early by letter of its proposed schedule of construction and expenditure.

2. If the nature of the issues warranted. discovery would be permitted on this schedule. and testimony would be required from applicant and staff (and permitted from intervenors) on the schedule. These steps would be taken toward the end of the hearing. and at the Licensing Board's discretion. The purpose of the testimony would be to identify points in the construction schedule which are critical for particular issues.

B. In the initial decision:

1. The Board would respond to the positions of the parties by ruling on the date when construction may begin. It would identify (and make findings on) any substantial issue which might be prejudiced by construction and note when construction might affect it.

2. The Licensing Board would defer construction whenever. as stated above. it found a substantial question (as defined above) on an issue which could be affected by construction. This decision would be made in light of the construction schedule. so that construction could go forward unless it affected an issue falling into the above categories. For example. where the issue is which is the best of several possible locations in a river bed for a discharge diffuser. early construction unrelated to the diffuser could not affect the ultimate resolution of that issue.

3. No construction could begin sooner than 30 days after the initial decision. This gives parties time to evaluate the decision and file papers before the Appeal Board.

C. On appellate review:

1. If an appeal is taken from the decision on effectiveness. 30 more days would be added to the period during which no construction could occur. During this total of 60 days the Appeal Board would be required to resolve the effectiveness question on appeal. The Appeal Board would use the same criteria for effectiveness as the Licensing Board. and the appeal would be limited to the effectiveness issue alone. Of course. if the Licensing Board had deferred effectiveness in its Initial Decision. these periods would be irrelevant. since construction could not begin until the date set by the Licensing Board. It could begin earlier only if the Appeal Board reversed the Licensing Board's deferral. Since it has the power to make such a reversal. the Appeal Board can. under Option A. take itself off the "critical path"—that is. remove itself as an obstacle to construction.

2. To allow for Commission review of effectiveness. a suitable period of deferral would be added at the conclusion of the Appeal Board's review.

3. Whenever effectiveness is deferred. the Appeal Board would resolve first. on the merits. all issues which had caused the deferral. It would decide other issues later. Construction could begin if and when the effectiveness-related issues were satisfactorily resolved on appeal.

Option B—A Final Decision on LWA Issues Prior to Construction

This option requires a final decision on the merits for construction-related issues before construction can begin. In essence. the Licensing Board would decide construction-related issues first. those issues would be taken up immediately on appeal. and construction would begin only after final appellate review of those issues. The issues are all those which. if resolved adversely to the applicant. would defeat the plant at the site selected or be prejudiced by the early stages of construction. They are generally the same as those now used for limited work authorizations (LWA_1 and LWA_2) and similar to those used in the standard suggested above in Option A for granting a stay. The main difference between this option and Option A is that here these issues are defined in advance. and must be resolved on the merits before construction. whereas in Option A the issues are not defined in advance and construction depends upon whether effectiveness is stayed pending appeal.

Final decision is required on all issues related to the National Environmental Policy Act (NEPA) and all safety issues related to site suitability and construction of foundations. The NEPA issues would be addressed as they are now for the LWA_1. For the site safety issues. however. the review would go beyond the present site suitability report and determine the design basis or bases for meeting the safety regulation pertinent to each issue. Thus. for each of the site safety issues. the staff and Licensing Board would complete in full the review currently included in the Safety Evaluation Report. This added scope of review should assure that all site-related issues are completely addressed and should solidify the basis for authorizing construction. The site safety issues would include:

(1) Geography and Demography.

(2) Nearby Industrial. Transportation and Military Facilities.

(3) Meteorology.

(4) Hydrology.

(5) Geology and Seismology.

(6) Foundation Engineering.

(7) Quality Assurance.

(8) Any other issue which. in the opinion of the presiding officer. is related to the commencement of construction at the site.

The remaining issues on the construction permit (CP) would be heard by the Licensing Board while the above issues were on appeal. The remaining CP issues would include:

(1) Design Criteria for Structures. Components. Equipment and Systems.

(2) Reactor and Reactor Coolant System.

(3) Engineered Safety Features.

(4) Instrumentation and Controls.

(5) Electrical Power.

(6) Auxiliary Systems.

(7) Steam and Power Conversion System.

(8) Radioactive Waste Management.

(9) Radiation Protection.

(10) Conduct of Operations.

(11) Initial Tests and Operations.

(12) Accident Analysis.

(13) Technical Specifications.

After appellate affirmance of the LWA issues. the applicant could do all the work authorized by LWA_1 and LWA_2. This includes site clearing. preparation and excavation (LWA_1) and safety-related foundations (LWA_2). Before this work is completed. the Licensing Board should have ample time to complete its hearing on the balance of the issues necessary for the construction permit. The grant of an LWA_2. which allows work on safety-related foundations. signifies clearly that all issues related to the safety of the site have already been resolved satisfactorily.

Option B would operate as follows:

a. At the hearing:

The Licensing Board takes up the LWA issues first. This is already the Board's practice where an LWA is requested. When decided. these issues are immediately ripe for appellate review. The Board's decision is not immediately effective. After deciding the LWA issues. the Licensing Board turns to the rest of the issues necessary for the CP. The LWA issues are processed on appeal while the rest of the CP issues are heard by the Licensing Board. If the intervenor's attorney is unable to pursue the appeal and continue the CP hearing at the same time, the Licensing Board suspends the CP hearing to allow for briefing time. The CP decision is normally made by the Licensing Board before construction ends under the LWA. If the applicant does not request a separate decision on LWA issues, effectiveness awaits appellate review of the CP decision. The issues which belong in the LWA category have been defined above, and are based upon actual experience in hearings. The Board rules on any dispute over which issues belong in the LWA category.

b. On appellate review:

1. The Appeal Board conducts an immediate review of the LWA issues, including disputes over which issues should be in the LWA category. Upon completing its review on the merits and rendering its opinion, the Appeal Board can authorize construction to begin. It can do so notwithstanding a remand for further proceedings on some minor issue (e.g., additional stations to monitor the effect of construction on muskrats). Basically, the requirement is that all construction-related issues on appeal must go through at least one merits review before construction.

2. To allow for Commission review, an additional period of deferral is added at the conclusion of the Appeal Board's review. The Commission decides whether to accept review during this period. If the Commission does accept review it can defer construction until the review is completed. Under this option, the Commission could review all construction-related issues on the merits before construction begins.

Option C—Repeal the Immediate Effectiveness Rule

This option prevents any construction prior to the agency's final decision on all issues. It does not rely upon stays to discriminate among cases, upon parties or the Licensing Board to identify the grounds for a stay, or upon an LWA or other device to identify certain issues for early treatment. The Commission would be able to pass on the merits of all issues before construction begins. Since construction does not begin until all CP issues are affirmed on appeal, the LWA procedures would not be used.

Option C would operate as follows:

a. At the hearing:

The Licensing Board conducts its usual review, but effectiveness does not attach to its CP authorization. Since construction cannot begin on the strength of an LWA, there is little incentive to seek one. The only possible advantage is to reduce the time required for the Appeal Board to review the CP decision, because by reviewing the LWA issues earlier fewer issues would remain on appeal of the CP.

b. On appellate review:

1. The Appeal Board must resolve all issues on the merits before construction begins. If an issue is remanded for further proceedings, the Appeal Board can, as in Option B above, decide whether to allow construction pending the remand.

2. To allow for Commission review, an additional period of deferral is added at the conclusion of the Appeal Board's review. The Commission decides whether to accept review during this period. If the Commission does accept review, it can defer construction until the review is completed. Under this option the Commission could review all issues in the case before construction begins.

Option D—Retain the Present System but With Significantly Loosened Standards for Obtaining a Stay

Under this approach, the standards for determining whether to grant a stay could be the same as those articulated under Option A, above—whether the party seeking the stay has demonstrated substantial, non-frivolous arguments for the correctness of its position on the merits of its appeal. The functional effect would be similar to that outlined for Option A, except that under this approach, it would be necessary for a party to seek a stay, whereas under Option A, the Board would examine the issue of effectiveness without the need for a party to make such a request. This would include a period of thirty (30) days after the date of service of the initial decision during which no construction could be commenced, so as to allow a party taking an appeal to prepare and present a stay request to the Appeal Board.

Option E.—Retain the present system unchanged

(See discussion of present system, above.)

Other Devices

In addition to the above options, the Commission is considering two devices—the increased use of referred rulings, and Commission monitoring of Licensing Board proceedings—which could aid either the present system or the implementation of any of the above options. These matters are described both in NUREG–0646 and in NUREG–0648, the study of the Commission's appellate system. (See "Supplementary Information", above.) Persons commenting on these devices may wish to refer to both studies.

Date of Implementation

The above options, if adopted, would be implemented by applying them to all applications for construction permits which have not begun hearings.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended and 5 U.S.C. 553, notice is hereby given that adoption of one of the following alternatives is contemplated.

A. *Option A.*

1. 10 CFR 2.760 is revised to read as follows:

§ 2.760 Initial decision and its effect.

(a) The presiding officer, after hearing, will render an initial decision which will constitute the final action of the Commission forty-five (45) days after its date, when it authorizes the issuance or amendment of a license for a facility, or thirty (30) days after its date in any other case, unless exceptions are taken in accordance with § 2.762, or the Commission directs that the record be certified to it for final decision.

(b) Where the public interest so requires, the Commission may direct that the presiding officer certify the record to it without an initial decision, and may:

(1) Prepare its own initial decision; or

(2) Omit an initial decision on a finding that due and timely execution of its functions imperatively and unavoidably so requires.

(c) An initial decision will be in writing and will be based on the whole record and supported by reliable, probative, and substantial evidence. The initial decision will include:

(1) Findings, conclusions and rulings, with the reasons or basis for them, on all material issues of fact, law, or discretion presented on the record;

(2) All facts officially noticed and relied on in making the decision;

(3) The appropriate ruling, order or denial of relief with the effective date;

(4) A separate finding, together with a statement of the basis for it, establishing the date upon which any construction authorized by the initial decision may begin;

(5) The time within which exceptions to the decision and a brief in support of them may be filed, the time within which briefs in support of or in opposition to exceptions filed by another party may be filed and, in the case of an initial decision which may become final in accordance with paragraph (a) of this section, the date when it may become final.

2. 10 CFR 2.764 is revised to read as follows:

§ 2.764 The commencement of construction under an initial decision authorizing construction or directing issuance or amendment of a construction permit.[1]

(a) Under an initial decision directing the issuance or amendment of a construction permit or a construction authorization for a production or utilization facility subject to the provisions of § 51.5(a) of this chapter.

(1) No person shall effect commencement of construction (as "commencement of construction" is defined in § 50.10(c) of this chapter) unless specifically so authorized by the Atomic Safety and Licensing Board. If the Board finds that no substantial question remains for appeal on an issue[2] related to the commencement of construction during appellate review, the Board shall authorize commencement of construction at the expiration of thirty (30) days after the date of service of the initial decision. In the event an appeal under this chapter is taken from such an initial decision authorizing commencement of construction, construction shall not commence within ninety (90) days after the date of service of the initial decision. If the Atomic Safety and Licensing Board, the Atomic Safety and Licensing Appeal Board, or the Commission finds that there is a substantial question on an issue related to the commencement of such construction, construction shall not commence until the merits of that issue are resolved on appeal. A "substantial question," for these purposes, does not require the Board to find that its own ruling may be incorrect, but rather that the party which did not prevail on the issue has demonstrated substantial, non-frivolous arguments which could be raised on appeal.

(b) The Director of Nuclear Reactor Regulation or the Director of Nuclear Material Safety and Safeguards, as appropriate, shall where authorized by an initial decision issue a construction permit or an amendment thereto or a construction authorization within 10 days after the date upon which commencement of construction is authorized pursuant to this chapter.

3. A new subparagraph (3) is added to § 2.785(b) of 10 CFR Part 2 to read as follows:

§ 2.785 Functions of Atomic Safety and Licensing Appeal Boards.

* * * * *

(b) * * *

* * * * *

(3) In a proceeding on appeal from an initial decision by an Atomic Safety and Licensing Board directing the issuance or amendment of a construction permit or construction authorization for a nuclear power reactor or testing facility:

(i) The Atomic Safety and Licensing Appeal Board shall, within 60 days after the date of service of the initial decision, complete its review of exceptions to that part of the initial decision of the Atomic Safety and Licensing Board which, under § 2.764, establishes the date upon which construction may commence. If no such exception is filed, the Atomic Safety and Licensing Appeal Board shall conduct any review of such part of the initial decision within 30 days of the date of service of that decision. The Atomic Safety and Licensing Appeal Board may extend these periods, but if it does so, it shall at the same time extend, by an equivalent amount, the thirty- (30-) day and ninety- (90-) day periods described in § 2.764(a).

(ii) After completing the review in paragraph (b)(3)(i) of this Section, the Atomic Safety and Licensing Appeal Board shall, if it finds that there is a substantial question on an issue related to the commencement of construction, undertake review on the merits of that issue on an expedited basis, and shall order that construction not commence pending completion of that expedited review.

4. A new paragraph (i) is added to 10 CFR 2.788 to read as follows:

§ 2.788 Stays of decisions of presiding officers and Atomic Safety and Licensing Appeal Boards pending review.

* * * * *

(i) The provisions of this section shall not apply to an initial decision directing the issuance or amendment of a construction permit or a construction authorization.

B. *Option B.*

1. 10 CFR 2.761a is revised to read as follows:

§ 2.761a Separate hearings and decisions.

In a proceeding on an application for a construction permit for a utilization facility which is subject to § 51.5(a) of this chapter, and is of the type specified in §§ 50.21(b) (2) or (3) or 50.22 of this chapter or is a testing facility, the presiding officer shall unless the parties agree otherwise or the rights of any party would be prejudiced thereby, commence a hearing on issues covered by § 50.10(e) and Part 51 of this chapter as soon as practicable after issuance by the staff of its final environmental impact statement and its final report on the site safety issues described in § 50.10(e), but no later than thirty (30) days after issuance of such statement and report, and complete such a hearing and issue an initial decision on such matters. Prehearing procedures regarding issues covered by Part 51 and § 50.10(e) of this chapter, including any discovery and special prehearing conferences and prehearing conferences as provided in §§ 2.740, 2.740a, 2.740b, 2.741, 2.742, 2.751a, and 2.752, shall be scheduled accordingly. The provisions of §§ 2.754, 2.755, 2.760, 2.762, 2.763, and 2.764 shall apply to any proceeding conducted and any initial decision rendered in accordance with this section. This section shall not preclude separate hearings and decisions on other particular issues.

2. 10 CFR 2.764 is revised to read as follows:

§ 2.764 Beginning construction under an initial decision directing issuance or amendment of a construction permit or a construction authorization.[3]

(a)(1) In a proceeding in which a construction authorization is granted by an initial decision rendered pursuant to § 2.761a of this part, no person shall effect commencement of construction (as "commencement of construction" is defined in § 50.10(c) of this chapter) or conduct any of the activities described in § 50.10(e)(1) within 30 days after the date of service of the decision by the Atomic Safety and Licensing Appeal Board reviewing on the merits any appeal filed under § 2.762 from that initial decision. If, after such a review, further proceedings are ordered, no person shall effect commencement of construction until authorized to do so by the Atomic Safety and Licensing Appeal Board. In granting or denying such an authorization, the Atomic Safety and Licensing Appeal Board shall consider the relative importance of the matter or matters remanded, and the extent to which the commencement of construction at the site during the pendency of the remand would cause serious environmental impacts to occur at the site or assets to be placed at risk. If a petition for review is filed with the Commission regarding this authorization, construction shall not commence within thirty (30) days after the date of service of the decision by the Atomic Safety and Licensing Appeal Board which grants the authorization.

(2) In a proceeding in which no construction authorization pursuant to § 2.761a is granted, and in which an initial decision directs the issuance or amendment of a construction permit, no person shall effect commencement of construction (as defined in § 50.10(c) of this chapter) within:

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[1] The temporary suspension of this rule in certain proceedings and related matters are addressed in Appendix B to this part.

[2] Such issues include, for example: Alternate sites, site suitability, and the overall NEPA cost-benefit balance.

[3] The temporary suspension of this rule in certain proceedings and related matters are addressed in Appendix B to this part.

(i) Thirty (30) days after the date of service of the decision by the Atomic Safety and Licensing Appeal Board reviewing on the merits at least that portion of any appeal from the initial decision which contains exceptions relating to the issues described by § 2.761a, or (ii) thirty (30) days after the date of the initial decision if no appeal from the initial decision is taken under this chapter.

(3) The initial decisions described in paragraphs (a) (1) and (2) of this section are appealable immediately in accordance with § 2.762 of this chapter.

(4) The Commission, pursuant to its appellate review under Part 2 of this chapter, may in its discretion extend any of the thirty- (30-) day periods described in paragraphs (a) (1) and (2) of this section.

(b) Where so authorized by an initial decision, the Director of Nuclear Reactor Regulation or the Director of Nuclear Material Safety and Safeguards, as appropriate, shall issue a construction permit or an amendment thereto or a construction authorization, as appropriate, within 10 days after the date upon which commencement of construction is authorized pursuant to paragraph (a) of this section.

3. A new subparagraph (3) is added to § 2.785(b) of 10 CFR Part 2 to read as follows:

§ 2.785 Functions of Atomic Safety Licensing Appeal Boards.

* * * * *

(b) * * *

* * * * *

(3) In a proceeding on appeal from an initial decision by an Atomic Safety and Licensing Board directing the issuance of a construction permit, the Atomic Safety and Licensing Appeal Board may in its discretion issue an early partial decision confined to the issues described in § 2.761a.

4. A new paragraph (i) is added to 10 CFR 2.788 to read as follows:

§ 2.788 Stays of decisions of presiding officers and Atomic Safety and Licensing Appeal Boards pending review.

* * * * *

(i) The provisions of this section shall not apply to an initial decision directing the issuance or amendment of a construction permit or a construction authorization.

5. Section 50.10(e) of 10 CFR Part 50 is amended to read as follows:

§ 50.10 License required.

* * * * *

(e)(1) The Director of Nuclear Reactor Regulation may authorize an applicant for a construction permit for a utilization facility which is subject to § 51.5(a) of this chapter, and is of the type specified in §§ 50.21(b) (2) or (3) or § 50.22 or is a testing facility, to conduct the following activities: (i) Preparation of the site for construction of the facility (including such activities as clearing, grading, construction of temporary access roads and borrow areas); (ii) installation of temporary construction support facilities (including such items as warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and construction support buildings); (iii) excavation for facility structures; (iv) construction of service facilities (including such facilities as roadways, paving, railroad spurs, fencing, exterior utility and lighting systems, transmission lines, and sanitary sewerage treatment facilities); (v) the installation of structural foundations, including any necessary subsurface preparation, for structures, systems and components which prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public; and (vi) the construction of structures, systems, and components which do not prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. No such authorization shall be granted unless the staff has completed a final environmental impact statement on the issuance of the construction permit as required by Part 51 of this chapter, and has completed its safety review so as to determine the design basis or bases for meeting the safety regulation pertinent to each of the following site safety issues: Geography and Demography; Nearby Industrial, Transportation and Military Facilities; Meteorology; Hydrology; Geology and Seismology; Foundation Engineering; and Quality Assurance.

(2) Such an authorization shall be granted only after the presiding officer in the proceeding on the construction permit application has made all the findings required by § 51.52 (b) and (c) of this chapter to be made prior to issuance of the construction permit for the facility, and has determined that there are no unresolved safety issues which relate to the installation of the structural foundations described in paragraph (e)(1)(v) of this section which would constitute good cause for withholding the authorization, and has made the findings under § 50.35 of this part required for the issuance of the construction permit with respect to the following site safety issues:

(i) Geography and Demography

(ii) Nearby Industrial, Transportation and Military Facilities

(iii) Meteorology

(iv) Hydrology

(v) Geology and Seismology

(vi) Foundation Engineering

(vii) Quality Assurance

(viii) Any other issue which, in the opinion of the presiding officer, is related to the commencement of construction at the site.

C. *Option C.*

1. 10 CFR 2.761a is deleted, and Appendix A to 10 CFR Part 2 is revised accordingly.

2. 10 CFR 2.764 is amended to read as follows:

§ 2.764 Commencement of construction under an initial decision directing issuance or amendment of a construction permit.

(a) In a proceeding in which an initial decision directs the issuance or amendment of a construction permit, no person shall effect commencement of construction (as "commencement of construction" is defined in § 50.10(c) of this chapter) within thirty (30) days after the date of service of the decision by the Atomic Safety and Licensing Appeal Board reviewing on the merits any appeal under § 2.762 from the initial decision. If, after such review, the initial decision is remanded for further proceedings before the Atomic Safety and Licensing Board, no person shall effect commencement of construction within thirty (30) days after the date set for commencement of construction by the Atomic Safety and Licensing Appeal Board. In setting this date, the Atomic Safety and Licensing Appeal Board shall consider the relative importance of the matter or matters remanded, and the extent to which the commencement of construction at the site during the pendency of the remand would cause assets to be placed at risk or serious environmental impacts to occur at the site.

(b) If no appeal is taken from the initial decision in paragraph (a) of this section, no person shall effect commencement of construction within thirty (30) days after the date of any decision by the Atomic Safety and Licensing Appeal Board reviewing the initial decision *sua sponte*, or within thirty (30) days after the date of the initial decision if no review *sua sponte* is undertaken.

(c) The initial decisions described in paragraph (a) of this section are *appealable immediately in accordance with § 2.762 of this chapter.*

(d) The Commission, *pursuant to its appellate review* under Part 2 of this chapter, may in its discretion extend any of the thirty- (30-) days periods in paragraph (a) of this section.

(e) Where so authorized by an initial decision, the Director of Nuclear Reactor Regulation or the Director of Nuclear Material Safety and Safeguards, as appropriate, shall issue a construction permit or an amendment thereto within 10 days after the date which the commencement of construction is authorized pursuant to paragraphs (a), (b) and (d) of this section.

3. A new paragraph (i) is added to 10 CFR 2.788 to read as follows:

§ 2.788 Stays of decisions of presiding officers and Atomic Safety and Licensing Appeal Boards pending review.

* * * * *

(i) The provisions of this section shall not apply to an initial decision directing the issuance or amendment of a construction permit.

§ 50.10 [Amended]

4. Section 50.10(e) of 10 CFR Part 50 is deleted.

D. *Option D.*

1. 10 CFR 2.764 is amended to read as follows:

§ 2.764 Commencement of construction under an initial decision directing issuance or amendment of a construction permit or a construction authorization.

(a) Under an initial decision directing the issuance or amendment of a construction permit or a construction authorization, no person shall effect commencement of construction (as "commencement of construction" is defined in § 50.10(c) within thirty (30) days after the date of service of the initial decision. In the event an appeal under Part 2 of this chapter is taken from the initial decision, no person shall effect commencement of construction within ninety (90) days after the date of service of the initial decision.

(b) The Director of Nuclear Reactor Regulation or the Director of Nuclear Materials Safety and Safeguards, as appropriate, shall where so authorized by an initial decision issue a construction permit, or an amendment thereto, or a construction authorization within ten (10) days after the expiration of the periods described in paragraph (a) of this section.

2. In § 2.788 of 10 CFR Part 2, paragraph (e) is revised and a new paragraph (i) is added to read as follows:

§ 2.788 Stays of decisions of presiding officers and atomic Safety and Licensing Appeal Boards pending review.

* * * * *

(e) Except as provided in paragraph (i) of this section, the Commission, the Atomic Safety and Licensing Appeal Board, or the presiding officer, in determining whether to grant or deny an application for a stay, will consider:

(1) whether the moving party has made a strong showing that it is likely to prevail on the merits;

(2) whether the party will be irreparably injured unless a stay is granted; (3) whether the granting of a stay would harm other parties; and (4) where the public interest lies.

* * * * *

(i) an application for a stay pending appeal of an initial decision directing issuance or amendment of a construction permit or a construction authorization shall be granted if the appeal presents a substantial question concerning an issue related to the commencement of construction.

Option E. Retain the present system unchanged. Relevant portions of the Commission's existing regulations are as follows:

§ 2.760 Initial decision and its effect.

(a) After hearing, the presiding officer will render an initial decision which will constitute the final action of the Commission forty-five (45) days after its date when it authorizes the issuance or amendment of a license or limited work authorization for a facility, or 30 days after its date in any other case, unless exceptions are taken in accordance with § 2.762 or the Commission directs that the record be certified to it for final decision.

(b) Where the public interest so requires, the Commission may direct that the presiding officer certify the record to it without an initial decision, and may:

(1) Prepare its own initial decision, which will become final unless exceptions are filed; or

(2) Omit an initial decision on a finding that due and timely execution of its functions imperatively and unavoidably so requires.

(c) An initial decision will be in writing and will be based on the whole record and supported by reliable, probative, and substantial evidence. The initial decision will include:

(1) Findings, conclusions and rulings, with the reasons or basis for them, on all material issue of fact, law, or discretion presented on the record;

(2) All facts officially noticed and relied on in making the decisions;

(3) The appropriate ruling, order or denial of relief with the effective date;

(4) The time within which exceptions to the decision and a brief in support of them may be filed, the time within which briefs in support of or in opposition to exceptions filed by another party may be filed and, in the case of an initial decision which may become final in accordance with paragraph (a) of this section, the date when it may become final.

§ 2.760a Initial decision in contested proceedings on applications for facility operating licenses.

In any initial decision in a contested proceeding on an application for an operating license for a production or utilization facility, the presiding officer shall make findings of fact and conclusions of law on the matters put into controversy by the parties to the proceeding and on matters which have been determined to be the issues in the proceeding by the Commission or the presiding officer. Matters not put into controversy by the parties will be examined and decided by the presiding officer only where he or she determines that a serious safety, environmental, or common defense and security matter exists. Depending on the resolution of those matters, the Director of Nuclear Reactor Regulation or Director of Nuclear Material safety and safeguards, as appropriate, after making the requisite findings, will issue, deny, or appropriately condition the license.

§ 2.761 Expedited decisional procedure.

(a) The presiding officer may determine a proceeding by an order after the conclusion of a hearing without issuing an initial decision, when:

(1) All parties stipulate that the initial decision may be omitted and waive their rights to file exceptions, to request oral argument, and to seek judicial review;

(2) No unresolved substantial issue of fact, law, or discretion remains, and the record clearly warrants granting the relief requested; and

(3) The presiding officer finds that dispensing with the issuance of the initial decision is in the public interest.

(b) An order entered pursuant to paragraph (a) of this section shall be subject to review by the Commission on its own motion within thirty (30) days after its date.

(c) An initial decision may be made effective immediately, subject to review by the Commission on its own motion within thirty (30) days after its date, except as otherwise provided in this chapter, when:

(1) All parties stipulate that the initial decision may be made effective immediately and waive their rights to file exceptions, to request oral argument, and to seek judicial review;

(2) No unresolved substantial issue of fact, or discretion remains and the record clearly warrants granting the relief requested; and

(3) The presiding officer finds that it is in the public interest to make the initial decision effective immediately.

(d) The provisions of this section do not apply to an initial decision directing the issuance or amendment of a construction permit or construction authorization, or the issuance of an operating license or provisional operating authorization.

§ 2.761a Separate hearings and decisions.

In a proceeding on an application for a construction permit for a utilization facility which is subject to § 51.5(a) of this chapter, and is of the type specified in §§ 50.21(b)(2) or (3) or 50.22 of this chapter or is a testing facility, the presiding officer shall, unless the parties agree otherwise or the rights of any party would be prejudiced thereby, commence a hearing on issues covered by § 50.10(e)(2)(ii) and Part 51 of this chapter as soon as practicable after issuance by the staff of its final environmental impact statement but no later than thirty (30) days after issuance of such statement and complete such a hearing and issue an initial decision on such matters. Prehearing procedures regarding issues covered by Part 51 and § 50.10(e)(2)(ii) of this chapter, including any discovery and special prehearing conferences and prehearing conferences as provided in §§ 2.740, 2.740a, 2.740b, 2.741, 2.742, 2.751a, and 2.752, shall be scheduled accordingly. The provisions of §§2.754, 2.755, 2.760, 2.762, 2.763, and 2.764(a) shall apply to any proceeding conducted and any initial decision rendered in accordance with this section. Paragraph 2.764(b) shall not apply to any partial initial decision rendered in accordance with this section. This section shall not preclude separate hearings and decisions on other particular issues.

§ 2.764 Immediate effectiveness of initial decision directing issuance or amendment of construction permit or operating license.

(a) An initial decision directing the issuance or amendment of a construction permit, a construction authorization or an operating license shall be effective immediately upon issuance unless the presiding officer finds that good cause has been shown by a party why the initial decision should not become immediately effective, subject to the review thereof and further decision by the Commission upon exceptions filed by any party pursuant to § 2.762 or upon its own motion.

(b) The Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards, as appropriate, notwithstanding the filing of exceptions, shall issue a construction permit, a construction authorization, or an operating license, or amendments thereto, authorized by an initial decision, within ten (10) days from the date of issuance of the decision.[1]

§ 2.785 Functions of Atomic Safety and Licensing Appeal Board.

(a) The Commission has authorized Atomic Safety and Licensing Appeal Board to exercise the authority and perform the review functions which would otherwise have been exercised and performed by the Commission, including, but not limited to, those under §§ 2.760–2.771, 2.912, and 2.913 in (1) proceedings on applications for licenses under Part 50 of this chapter and (2) such other licensing proceedings under the regulations in this chapter as the Commission may specify.

(b)(1) In the proceedings described in paragraph (a) of this section, the Atomic Safety and Licensing Appeal Board will also exercise the authority and perform the functions which would otherwise have been exercised and performed by the Commission under §§ 2.711, 2.717(a), 2.718(i), 2.720(f), 2.730, 2.742(b), 2.743(b), 2.752(a) and (c) and Subpart I, except those functions referred to in § 2.905(c), (e)(2), (g), and (h)(2).

(2) In a proceeding on an application for an operating license where the Atomic Safety and Licensing Appeal Board determines that a serious safety, environmental, or common defense and security matter exists that has not been raised by the parties, it may give appropriate consideration to that matter.

(c) In the proceedings described in paragraph (a) of this section, the Atomic Safety and Licensing Appeal Board shall exercise the authority and perform the functions delegated to it subject to the provisions and limitations of the referenced sections and subpart. Except as provided in § 2.786, any action taken by the Atomic Safety and Licensing Appeal Board pursuant to its delegated authority shall have the same force and effect and shall be made, evidenced, and enforced in the same manner as actions of the Commission.

(d) In the proceedings described in paragraph (a) of this section, an Atomic Safety and Licensing Appeal Board may, either in its discretion or on direction of the Commission, certify to the Commission for its determination major or novel questions of policy, law or procedure.

§ 2.788 Stays of decisions of presiding officers and Atomic Safety and Licensing Appeal Boards pending review.

(a) Within ten (10) days after service of a decision or action any party to the proceeding may file an application for a stay of the effectiveness of the decision or action pending filing of and decision on an appeal or petition for review. Except as provided in paragraph (f) of this section, such an application may be filed with the Commission, Atomic Safety and Licensing Appeal Board, or the presiding officer.

(b) An application for a stay shall be no longer than ten (10) pages, exclusive of affidavits, and shall contain the following:

(1) A concise summary of the decision or action which is requested to be stayed;

(2) A concise statement of the grounds for stay, with reference to the factors specified in paragraph (e) of this section;

(3) In the case of an application to the Commission for stay of decisions or actions by an Atomic Safety and Licensing Appeal Board, a statement where (including record citation, if available) a stay was requested from the Appeal Board and denied. If no such request was made of the Appeal Board, the application should state why it could not have been made; and

(4) To the extent that an application for a stay relies on facts subject to dispute, appropriate references to the record or affidavits by knowledgeable persons.

(c) Service of an application for a stay on the other parties shall be by the same method, e.g., telegram, mail, as the method for filing the application with the Commission, Atomic Safety and Licensing Appeal Board, or the presiding officer.

(d) Within ten (10) days after service of an application for a stay under this section, any party may file an answer supporting or opposing the granting of a stay. Such answer shall be no longer than ten (10) pages exclusive of affidavits, and should concisely address the matters in paragraph (b) of this section to the extent appropriate. No further replies to answers will be entertained. Filing of and service of an answer on the other parties shall be by the same method, e.g., telegram, mail, as the method for filing the application for the stay.

(e) In determining whether to grant or deny an application for a stay, the Commission, Atomic Safety and Licensing Appeal Board, or presiding officer will consider:

(1) Whether the moving party has made a strong showing that it is likely to prevail on the merits;

(2) Whether the party will be irreparably injured unless a stay is granted;

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[1] The temporary suspension of this rule in certain proceedings and related matters are addressed in Appendix B to this part

(3) Whether the granting of a stay would harm other parties; and

(4) Where the public interest lies.

(f) An application to the Commission for a stay of a decision or action by an Atomic Safety and Licensing Appeal Board will be denied if a stay was not, but could have been, sought before the Appeal Board. An application for a stay of a decision or action of a presiding officer may be filed before either the Atomic Safety and Licensing Appeal Board or the presiding officer, but not both at the same time.

(g) In extraordinary cases, where prompt application is made under this section, the Commission, Atomic Safety and Licensing Appeal Board, or presiding officer may grant a temporary stay to preserve the status quo without waiting for filing of any answer. The application may be made orally provided the application is promptly confirmed by telegram. Any party applying under this paragraph shall make all reasonable efforts to inform the other parties of the application, orally if made orally.

(h) A party may file an application for a stay of a decision or action granting or denying a stay. As to a decision or action of a presiding officer the application shall be filed with the Atomic Safety and Licensing Appeal Board. As to a decision or action of the Atomic Safety and Licensing Appeal Board the application shall be filed with the Commission. In each case the procedures and criteria of §§ 2.788(a)–(e) shall be followed.

45 FR 50349

Published 7/29/80

Comment period extended to 7/21/80

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10 CFR Parts 2 and 50

Possible Amendments to "Immediate Effectiveness" Rule

AGENCY: Nuclear Regulatory Commission.

ACTION: Extension of Period for Public Comment on Proposed Rulemaking.

SUMMARY: The Commission is extending the time for comments on its notice of proposed rule making on its "immediate effectiveness" rule. That rule provides that construction on a nuclear power plant can begin on the basis of an initial decision by an Atomic Safety and Licensing Board even though that decision is subject to further review within the Commission.

DATE: Comment period, as extended, expires July 21, 1980.

FOR FURTHER INFORMATION CONTACT: Mr. Peter G. Crane (202) 634–3288.

SUPPLEMENTARY INFORMATION: **On May 22, 1980, the Commission published a notice in the Federal Register (45 FR 34279) requesting comments by July 7, 1980 on a proposed rulemaking concerning possible amendments to the Commission's "immediate effectiveness" rule. On July 6, 1980, Mr. Malcolm H. Philips, Jr. requested a two-week extension of the comment period to July 21, 1980. The Secretary of the Commission, under the authority contained in 10 CFR 2.808, has granted Mr. Philips' request. Accordingly, the time for interested persons to submit written comments to Mr. Samuel J. Chilk, Secretary, United States Nuclear Regulatory Commission, Washington, D.C. 20555, has been extended to July 21, 1980.**

46 FR 30349

Published 6/8/81

Comment period expires on 6/29/81.

No requests for extensions of time will be granted.

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10 CFR Part 2

Rules of Practice for Domestic Licensing Proceedings; Modifications to the NRC Hearing Process

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission is considering several amendments to its Rules of Practice to facilitate expedited conduct of its adjudicatory proceedings. These amendments would require a person seeking intervention in formal NRC hearings to set forth the facts on which the contentions are based and the sources or documents used to establish those facts, limit the number of interrogatories that a party may file on another party in an NRC proceeding, and permit the boards to require oral answers to motions to compel and service of documents by express mail. An alternative formulation of the amendments would also require an increased threshold showing in support of a contention as a prerequisite to admission for hearing.

DATES: Comment period expires on June 29, 1981. No requests for extensions of time will be granted.

ADDRESSES: All interested persons who desire to submit comments in connection with the proposed amendments should send them to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch. Copies of comments on the proposed amendments may be examined at the Commission's Public Document Room at 1717 H Street, N.W., Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Martin G. Malsch, Esq., Deputy General Counsel, U.S. Nuclear Regulatory Commission, Washington, D.C 20555 (202) 634–1465.

SUPPLEMENTARY INFORMATION: In recent weeks the Commission has been examining its hearing process to determine if there are means to expedite the hearing process without reducing its quality or fairness. As a result of this review the Commission has sought comment on several proposed amendments to 10 CFR Part 2, the Commission's Rules of Practice (46 FR 17216, March 18, 1981) and issued a "Statement of Policy on the Conduct of Licensing Proceedings." The Commission is soliciting comments on the following additional changes to the Commission's Rules of Practice:

1. Intervention in NRC Proceedings

Formal administrative hearings are always conducted by NRC as part of its proceedings on applications for construction permits for nuclear power plants and frequently on applications for operating licenses and license amendments. Any member of the public whose interest may be affected by the proceeding is entitled to participate in NRC hearings under 10 CFR 2.714 and section 189a of the Atomic Energy Act (42 U.S.C. 2239a).

The Commission is concerned that its present intervention process is not satisfactorily serving the public's interest in efficient resolution of nuclear plant licensing issues. Trial-type hearings are generally acknowledged as best-suited for the resolution of contested factual issues. Thus, one means to more efficient decisionmaking is to reduce the possibility that time and resources may be expended by the parties and hearing tribunals in a proceeding on issues that do not involve material factual disputes. To this end, the proposed amendment seeks to relate the Commission's rules on intervention (10 CFR 2.714) more clearly and directly to the fact-oriented character of NRC licensing hearings. Under the proposal, a person who petitions to intervene and request a hearing would be required to set forth at the outset the facts on which the contention is based and the sources or documents used or intended to be used to establish those facts. This requirement would give other parties early notice of an intervenor's case so as to afford opportunity for an early motion for summary disposition where there is no factual dispute. The Commission official designated to rule on intervention questions could dismiss or otherwise impose a sanction respecting any petition, request, or contention that is found not to satisfy the requirement.

The Atomic Energy Act of 1954, as amended (42 U.S.C. 2239a) provides that "the Commission shall grant a hearing upon the request of any person whose interest may be affected by the proceeding, and shall admit any such person as a party to such proceeding." Commission rules for intervention (10 CFR 2.714(b)) further provide that a person who petitions to intervene in a proceeding must later submit "a supplement to his petition to intervene which must include a list of contentions which petitioner seeks to have litigated * * * and the bases for each contention set forth with reasonable specificity." To participate as a party, the petitioner must advance at least one contention that satisfies this requirement. The requirement of a list of contentions was intended to serve as the mechanism by which a would-be intervenor informs the parties to the proceeding and the hearing tribunal of the issues upon which the intervenor wishes to be heard. The list of contentions, in turn, was intended to crystallize the question whether such issues are germane to matters properly within the scope of the proceeding as set out in the notice of hearing or notice of opportunity for hearing. Admitted contentions are included as matters in controversy in a proceeding and, thus, govern the scope of administrative discovery under 10 CFR 2.740(b)(1).

Under present practice, the Commission official designated to rule on intervention questions examines each contention to determine whether (1) the contention is stated with the requisite specificity, (2) the basis is adequately delineated, and (3) the issue sought to raised is cognizable in an individual licensing proceeding. *Alabama Power Co.* (Joseph M. Farley Nuclear Plant, Units 1 and 2), ALAB–182, 7 AEC 210, 216–17 (1974).

The examination is limited to what appears within the four corners of the contention as stated. No inquiry is made into the merits of the contention. All that is required is that the petitioner "state his reasons (i.e., the basis) for his contention * * *." *Houston Lighting and Power Co.* (Allens Creek Nuclear Generating Station, Unit 1), ALAB–590, 11 NRC 542, 548 (1980). The petitioner is under no obligation to demonstrate the existence of some factual support for a contention, as a precondition to its acceptance under 10 CFR 2.714. That obligation currently arises later in the proceeding, either in opposition to a motion for summary disposition filed by another party (10 CFR 2.749) or at the evidentiary hearing. ALAB–590 *supra*, 11 NRC at 549–51.

Under the proposed amendment, an interested person petitioning to intervene in an NRC licensing proceeding and requesting a hearing must set forth in the supplement required by 10 CFR 2.714(b) a concise statement of the facts supporting each contention together with references to the specific sources and documents which have been or will be relied on to establish such facts. Thus, the amendment would strengthen one of the purposes of the present rule, which is to give notice to the parties and the adjudicatory board of a would-be intervenor's concern, by also requiring notice of (1) the facts on which the concern is based, and (2) the sources or references which have been or will be used to establish those facts. References by title to lengthy or general studies and reports would not suffice. If, for example, the BEIR Report or the Reactor Safety Study is relied upon, specific portions of the document must be referenced.

The amendment would permit the staff or applicant to seek and the presiding NRC official to compel a more specific or definite statement if the would-be intervenor (1) fails to submit any facts, sources, or references at all, or (2) submits purported facts, sources, or references which are so vague as to give inadequate notice. The presiding officer would have the authority to impose appropriate sanctions against a person whose supplement failed to satisfy the proposed requirement, including the power to dismiss a contention. As under existing practice, a person who fails to file a supplement which satisfies the requirement with respect to at least on contention would not be permitted to participate as a party. See 10 CFR 2.714(b).

The proposed changes does not permit the NRC official authorized to rule on petitions for intervention to consider whether the facts, sources, or references contained in a supplement are legally sufficient to prove the contention. However, an obviously insufficient factual or evidentiary basis could prompt the staff or applicant to move early for summary disposition.

In recognition that one purpose of the contention process is to help frame the scope of subequent proceedings, an intervenor admitted to a proceeding would not be permitted, absent good cause, to seek or establish facts or rely on sources as to which notice was not given when the contention was admitted. However, an intervenor would not be limited to the facts, sources, and references identified in his supplement if he can show good cause such as, for example, newly discovered facts, sources, or references not reasonably available when the contention was admitted.

The Commission believes that the proposed amendment would not unlawfully restrict the intervention rights provided by the Atomic Energy Act of 1954 (42 U.S.C. 2239a) or the Administrative Procedure Act (5 U.S.C. 554–557). The amendment is intended to curtail an intervenor's right to participate only on these issues where the intervenor fails to identify the facts, sources, and references on which the intervenor has or will rely for the contention.

A member of the public has no absolute or unconditional right to intervene in a nuclear power plant licensing proceeding under the Atomic Energy Act. *BPI* v. *Atomic Energy Commission*, 502 F. 2d 424 (D.C. Cir. 1974). Section 189a of the Act which provides for intervention is subject to the Commission's rulemaking power under section 161p and, thus, to reasonable procedural requirements designed to further the purposes of the Act. *BPI* v. *Atomic Energy Commission, supra*, 502 F. 2d at 427, 428; *see also American Trucking Ass'ns, Inc.* v *United States*, 627 F. 2d 1313, 1320–23 (D.C. Cir. 1980). Furthermore, the right to intervention under section 189a for a member of the public is explicitly conditioned upon a "request." The proposed amendments would, in effect, provide that a "proper request" by a member of the public shall include a statement of the facts supporting each contention together with references to the sources and documents on which the intervenor relies to establish those facts. Finally, the Administrative Procedure Act creates no independent right to intervene in nuclear licensing proceedings. See *Easton Utilities Commission* v. *Atomic Energy Commission*, 424 F. 2d 847, 852 (D.C. Cir. 1970) (en banc); cf. *National Coal Operators' Assn.* v. *Kleepe*, 423 U.S. 388, 398–99, 46 L. Ed. 2d 580, 96 S. Ct. 809 (1976).

Comments also are requested on an alternative amendment to the rules on intervention that would impose additional requirements on persons seeking to intervene in nuclear licensing hearings. In particular, would-be intervenors could not have a contention admitted for hearing under the alternative formulation if the documents and other information submitted fail to demonstrate that there exists a genuine issue of material fact to be heard. The NRC official authorized to rule on intervention matters could use his or her technical knowledge in deciding whether a genuine issue of fact exists. Further, the alternative amendment would require the facts asserted in support of a contention to be sufficient to state a *prima facie* case. Finally, a contention raising only an issue of law would not be admitted for hearing but, rather, would be decided on the basis of briefs and/or oral argument in accordance with procedures to be established by the NRC presiding officer.

2. Limit on Interrogatories

Currently, parties to NRC proceedings may file interrogatories on the other parties without any specific limit. The Commission is requesting comment on a proposed rule which would provide that unless leave to file additional interrogatories is granted by a licensing board, parties may not file more than 50 interrogatories on another party in a single NRC proceeding. This rule would apply to all NRC proceedings including hearings on construction permit and operating license applications, license amendment proceedings, antitrust hearings, and enforcement proceedings. For purposes of the rule, in determining what constitutes an interrogatory, each subpart of a question (whether or not designated as such) would be considered as an interrogatory, except that requests for supporting reasoning relied upon or the name of a witness who will testify on a matter covered by an interrogatory response will not count as separate interrogatories. The rule would be applied in NRC proceedings prospectively. Thus, regardless of how many interrogatories a party has filed prior to the effective date of the rule, it could still file an additional 50 interrogatories on each party if the period for discovery has not been closed.

The Board may grant requests to file interrogatories exceeding the limit set forth in the rule if it determines that: (a) a response to the extra interrogatories is essential for the party to adequately prepare its case, taking into account the number of contentions in the proceeding, the complexity of issues, and timing of issuance and number of staff/applicant documents; (b) the information sought is not otherwise reasonably available; and (c) the party was not improvident in its overall use of its first 50 interrogatories. This rule is designed to alleviate strains placed on the resources of the participants in NRC proceedings when an inordinate number of interrogatories are filed. In recent years, more than 20 United States district courts have adopted rules which similarly limit the number of interrogatories that may be filed on a party without leave of the court.

Even if this rule is adopted, the NRC staff would continue its practice of voluntarily making pertinent staff documents available to the public, and responding to requests for production of documents under 10 CFR 2.741 and the Freedom of Information Act.

3. Motions to Compel Discovery

Under the Commission's current regulations, parties may file responses to motions to compel. To expedite NRC proceedings, the Commission is proposing amendments to its regulations which would provide the Boards with the discretion to order that the responses be made orally in a conference telephone call or other prehearing conference, rather than in writing.

4. Service

The Commission is also proposing to permit its licensing boards to require service of documents by express mail (next day delivery). Currently, the Commission's rules provide five days for service of documents. Use of express mail in limited circumstances could reduce this time to two days.

The Commission would expect express mail delivery to be required only in those proceedings where it appears that construction of a facility may be finished prior to the completion of the operating license proceedings, or other similar circumstances where expedition is especially important. Because of the expense of express mail delivery, parties should be required to use that form of service only on those parties who are required to respond to the pleading being served. For example, a party may be required to file interrogatories on a party by express mail, but should not be required to express mail copies of the interrogatories to the Board or to the parties to the proceeding which are not being asked to respond to the interrogatories. Alternatively, if a party prefers not to use express mail, when so ordered by the Board, it could use first class mail and file its document three days earlier.

Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission hereby certifies that this rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. This rule affects the Commission's rules of practice and procedures by permitting expedition of the licensing process.

Proposed Regulatory Changes

Pursuant to the Atomic Energy Act of 1954, as amended, the energy Reorganization Act of 1974, as amended, and section 553 of the United States Code, notice is hereby given that adoption of the following amendments to 10 CFR Part 2 are contemplated.

PART 2—RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS

1. *Option A:* In § 2.714, paragraph (b) is revised to read as follows:

§ 2.714 Intervention.

* * * * *

(b) Not later than fifteen (15) days prior to the holding of the special prehearing conference pursuant to § 2.751a, or where no special prehearing conference is held, fifteen (15) days prior to the holding of the first prehearing conference, the petitioner shall file a supplement to his petition to intervene which must include a list of the contentions which petitioner seeks to have litigated in the matter, and the bases for each contention set forth with reasonable specificity. The supplement must set forth a concise statement of the facts supporting each contention together with references to the specific sources and documents and portions thereof which have been or will be relied upon to establish such facts. A petitioner who fails to file such a supplement which satisfies the requirements of this paragraph with respect to at least one contention will not be permitted to participate as a party. Additional time for filing the supplement may be granted based upon a balancing of the factors in paragraph (a)(1) of this section.

Option B: In § 2.714, paragraph (b) is revised to read as follows:

§ 2.714 Intervention.

* * * * *

(b)(1) Not later than fifteen (15) days prior to the holding of the special prehearing conference pursuant to § 2.751a, or where no special prehearing conference is held, fifteen (15) days prior to the holding of the first prehearing conference, the petitioner shall file a supplement to his petition to intervene which must include a list of the contentions which petitioner seeks to have litigated in the matter, and the bases for each contention set forth with reasonable specificity. The supplement must set forth a concise statement of the facts supporting each contention together with references to the specific sources and documents and portions thereof which have been or will be relied upon to establish such facts. A petitioner who fails to file such a supplement which satisfies the requirements of this paragraph with respect to at least one contention will not be permitted to participate as a party. Additional time for filing the supplement may be granted based upon a balancing of the factors in paragraph (a)(1) of this section.

(2) A contention shall not be admitted for hearing if the documents and other information submitted under paragraph (1) of this subsection fail to demonstrate that there is a genuine issue of material fact to be heard. In particular, failure to make such a submission or vagueness of the contention is sufficient ground for rejection.

(3) In making the decision as to whether a genuine issue of material fact exists, the members of the Boards may use their technical knowledge to judge the merit of the contention.

(4) A contention raising only an issue of law shall be decided on the basis of briefs or oral argument in accordance with procedures to be established by the presiding officer or the Board.

(5) A contention shall not be admitted if the facts asserted are legally insufficient to support the contention or if the contention is immaterial or irrelevant to the proposed action which is before the presiding officer or the Board.

2. Section 2.710 is revised to read as follows:

§ 2.710 Computation of time.

In computing any period of time, the day of the act, event, or default after which the designated period of time begins to run is not included. The last day of the period so computed is included unless it is a Saturday, Sunday, or legal holiday at the place where the action or event is to occur, in which event the period runs until the end of the next day which is neither a Saturday, Sunday, nor holiday. Whenever a party has the right or is required to do some act or take some proceeding within a prescribed period after the service of a notice or other paper upon him and the notice or paper is served upon by mail, five (5) days shall be added to the prescribed period. Only two (2) days shall be added when a document is served by express mail.

3. In § 2.712, paragraph (c) is revised to read as follows:

§ 2.712 Service of papers, methods, proof.

* * * * *

(c) How Service may be made. Service may be made by personal delivery, by first class, certified or registered mail including air mail, by telegraph, or as otherwise authorized by law. Where there are numerous parties to a proceeding, the Commission may make special provision regarding the service of papers. The presiding officer may require service by express mail.

* * * * *

4. In § 2.720, paragraph (h)(2)(ii) is revised to read as follows:

§ 2.720 Subpoenas.

* * * * *

(h) * * *

(2) * * *

(ii) In addition, a party may file with the presiding officer written interrogatories to be answered by NRC personnel with knowledge of the facts designated by the Executive Director for Operations. Upon a finding by the presiding officer that answers to the interrogatories are necessary to a proper decision in the proceeding and that answers to the interrogatories are not reasonably obtainable from any other source, the presiding officer may require that the staff answer the interrogatories. The limits on the number of interrogatories that may be served on a party pursuant to § 2.740b apply to the staff.

* * * * *

5. In § 2.730, paragraph (h) is added which reads as follows:

§ 2.730 Motions.

* * * * *

(h) Where the motion in question is a motion to compel discovery under this section or § 2.740(f), parties may file answers to the motion pursuant to paragraph (c) of this section. The Board, in its discretion, may order that the answer be given orally during a telephone conference or other prehearing conference, rather than in writing.

* * * * *

6. In § 2.740b, paragraph (c) is added which reads as follows:

§ 2.740b Interrogatories to parties.

* * * * *

(c) No party may file more than fifty (50) interrogatories on another party during the course of the proceeding, unless leave to do so is granted by the presiding officer. For purposes of this section each subpart of a question (whether or not designated as such) is considered as an interrogatory, except that requests for supporting reasoning relied upon or the name of a witness who will testify on a matter covered by an interrogatory response will not count as separate interrogatories. The Board will grant leave to file additional interrogatories if it determines that: (1) response to the extra interrogatories is essential for a party to prepare adequately its case, taking into account the number of contentions in the proceeding, the complexity of issues, and timing of issuance and number of staff/applicant documents; (2) the information sought is not otherwise reasonably available; and (3) the party was not improvident in its overall use of its first 50 interrogatories.

Dated at Washington, D.C. this 3rd day of June, 1981.

For the Commission.

Samuel J. Chilk,

Secretary of the Commission.

46 FR 53189
Published 10/28/81
Comment period expires 11/27/81.
Comments received after this date
will be considered if practical to do
so but assurance of consideration
cannot be given except to camments
received on or before this date.

10 CFR Parts 1 and 2

Procedures Involving the Equal Access to Justice Act: Implementation

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Commission proposes to amend its rules of practice to add new provisions designed to implement the recently enacted Equal Access to Justice Act, Pub. L. No. 96-481. That Act provides for the award of fees and expenses to certain individuals and businesses that prevail in agency adjudications in which the agency's position is determined not to have been substantially justified. The basis for these proposed regulations is a set of model rules issued by the Administrative Conference of the United States, which have been modified to conform to the Nuclear Regulatory Commission's established rules of practice.

DATE: Comment period expires November 27, 1981. Comments received after this date will be considered if practical to do so but assurance of consideration cannot be given except to comments received on or before this date.

ADDRESSES: Written comments should be submitted to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC, 20555, Attn: Docketing and Service Branch. Copies of all comments received may be examined and copied for a fee in the Commission's Public Document Room at 1717 H Street, N.W., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Paul Bollwerk, Esq., Office of the General Counsel, (202) 634-3224, U.S. Nuclear Regulatory Commission, Washington, DC, 20555.

SUPPLEMENTARY INFORMATION:

I. Background

On October 21, 1980, President Carter signed into law Equal Access to Justice Act (EAJA), Pub. L. No. 96-481, 94 Stat. 2325, 5 U.S.C. § 504. Under its terms, which become effective October 1, 1981, individuals and business entities meeting certain net worth and other requirements may be awarded fees and expenses incurred in connection with agency "adversary adjudications" if they prevail over the agency unless the presiding adjudicatory official determines that the agency's position was substantially justified or that special circumstances preclude an award as unjust. 5 U.S.C. 504(a). The Act also provides that each agency, after consultation with the Administrative Conference of the United States (ACUS), is to establish uniform procedures for the submission and consideration of applications for awards of fees and expenses. *Id.* § 504(c)(1). To facilitate this statutory requirement, ACUS developed and issued model rules for consideration and utilization by those agencies affected by the EAJA's requirements. 46 FR 15895 (March 10, 1981) and 46 FR 32900 (June 25, 1981). The basis for the rules now proposed by the Nuclear Regulatory Commission (NRC) are those ACUS model rules, except to the extent, as more fully explained herein, they are deemed unnecessary or not consistent with present NRC procedure. The proposed rules, if adopted, will be added to the Commission's regulations in 10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings," as a new subpart J and will apply to adversary adjudications pending before the NRC on October 1, 1981, or thereafter. In addition certain minor changes would be made to 10 CFR Part 1 and other sections of Part 2 to indicate the role of the Atomic Safety and Licensing Board and the Atomic Safety and Licensing Appeal Board in ruling on EAJA applications.

II. Section-by-Section Analysis

Proposed § 2.1000 is a compilation of §§ 0.101-.103 of the ACUS Model Rules and is designed to give a general overview of the proceedings covered by the EAJA. Much of §§ 0.101-.103 of the Model Rules is a restatement of the terms of the Act, which has been omitted. Retained and modified, however, are the Model Rules provisions dealing with those agency proceedings that are to be deemed "adversary adjudications" such that the EAJA is applicable. As a recent information paper submitted to the Commission from the Office of the General Counsel (OGC) and the Office of the Executive Legal Director (OELD) indicates, the EAJA, which applies to proceedings that are required by statute to be conducted on the record, appears to encompass only NRC proceedings relating to the modification, suspension, or revocation of reactor licenses. SECY-81-169, at 3-4 & n.4.[1] See also U.S. Dep't of Justice, *Attorney General's Manual on the Administrative Procedure Act,* 41-43 (1947). Although the ACUS Model Rules suggest that all covered proceedings should be listed in the agency's rules, as was noted in SECY-81-169, there is no definitive answer about the EAJA's applicability to proceedings concerning domestic materials licenses. The Commission, therefore, has decided to include only language delineating the general statutory exemption for proceedings granting or renewing licenses without indicating what specific types of licensing action are involved.[2]

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[1] In addition, as the OGC/OELD paper concluded, the EAJA does not apply to proceedings involving import and export licenses. Likewise, although SECY-81-169 concluded that the EAJA might be applicable to contract dispute proceedings before an agency Board of Contract Appeals, the comments to the ACUS Model Rules indicate otherwise, 46 F.R. at 32901-02, and accordingly no specific mention of such proceedings is considered necessary.

Copies of SECY-81-169 are available for inspection and may be copied for a fee in the Commission's Public Document Room at 1717 H Street, N.W., Washington, DC.

[2] SECY-81-169 expressed some uncertainty about whether the EAJA applied to civil penalty proceedings under 10 CFR 2.205 because an opportunity for a hearing is provided by rule rather than required by statute. However, in response to comments on its proposed Model Rules, ACUS dropped a provision suggesting that awards would be available when agencies voluntarily held on the record hearings and acknowledged that the EAJA should be considered to apply only when a formal hearing is a statutory or constitutional requirement. 46 F.R. at 32901.

Proposed § 2.1001 corresponds to § 0.104 of the ACUS Model Rules and denotes the eligibility requirements for award applicants.

Minor changes include the rewording of § 2.1001(a) to indicate more specifically that the types of applicants are limited, the addition of an example to § 2.1001(e) to show how part-time employees are to be counted, and the substitution of the term "presiding officer" for the statutory term "adjudicative officer" in § 2.1001(f). The last change, which has been implemented throughout the remainder of the proposed rule, is in line with the use of the term "presiding officer" in 10 CFR Part 2 to designated the Atomic Safety and Licensing Board, Administrative Law Judge, or other adjudicative official having the designated responsibility for rendering an initial agency decision.

Proposed § 2.1002, which corresponds to ACUS Model Rule § 0.105 and restates the statutory standard for awards, is unchanged except for the substitution of the term "agency staff" for "agency counsel" to conform the language to NRC practice. Similar conforming changes have been made throughout the proposed rules.

Revisions to ACUS Model Rules § 0.106, which is § 2.1003 of the NRC's proposed rule and relates to allowable fees and expenses, are also mostly minor grammatical and conforming changes. Contrary to the suggestion in § 0.106(b) of the Model Rules, however, no exact figure has been provided in the proposed § 2.1003(b) for the highest rate of compensation for expert witnesses because that figure, dependent as it is on the highest rate at which NRC pays its expert witnesses, potentially would be subject to numerous changes and is otherwise available from the agency.

Proposed § 2.1004 corresponds to ACUS Model Rules § 0.107 and sets forth procedures for rulemaking proceedings, as are referenced in the EAJA, 5 U.S.C. § 504(b)(1)(A)(ii), for raising the $75 per hour cap on attorney or agent fees. Any petition for rulemaking on this subject will be handled in conformity with 10 CFR 2.802.

Proposed § 2.1005, which corresponds to ACUS Model Rule § 0.108, provides for an award against an agency of the United States other than the NRC in those rare instances in which another agency participates in an NRC proceeding that is subject to the EAJA.

Proposed § 2.1006, which corresponds to § 0.109 of the ACUS Model Rules, is a general Commission delegation of authority to presiding officers, including the Atomic Safety and Licensing Board, and the Atomic Safety and Licensing Appeal Board to take final action with regard to EAJA matters in adversary adjudications that may be before them. This is in conformity with existing Commission practice regarding reactor licensing matters, *see* 10 CFR 2.721, 2.760, 2.785, and is subject to any other designation the Commission may make in a particular instance.

Sections 2.1010–.1013 of the proposed rules, the agency's counterparts to ACUS Model Rules §§ 0.201–.204, have been adopted from the ACUS suggestions almost *in toto* with only two changes of substance. The purpose of these sections is to set out in detail the information that must be submitted to the agency by applicants for awards under the EAJA as well as when such applications should be filed. The first change, which is in proposed § 2.1013(b), is an additional sentence not found in § 0.204(b) of the Model Rules that specifically indicates that judicial review of the final decision on the underlying controversy before the agency would stay any filing of an EAJA claim with the NRC. In that event, any EAJA award would be determined in accordance with the Act's provisions concerning judicial review of adversary adjudications, 28 U.S.C. 2412(d)(3); 5 U.S.C. 504(c)(1).

Special mention also should be made of § 2.1011(b), which seeks to provide for confidential treatment of financial information submitted to the agency. Although the NRC General Counsel in comments on the proposed ACUS Model Rules expressed some doubt about the ability of any agency to protect such information from disclosure under the Freedom of Information Act (FOIA), nonetheless, in the absence of any specific statutory FOIA exclusion for such information, the proposed rule appears to present the best method of dealing with the potential problem by providing the agency with the information it is most likely to need in handling any FOIA request for financial information deemed by the presiding officer to be confidential. In addition, the second change mentioned has been made in this § 2.1011 (b) by the addition of procedures to allow all parties to receive and comment upon an applicant's motion for nondisclosure and to allow the applicant, in the event of a finding that its net worth information will not be withheld, to receive back the information and withdraw its application. This latter provision is similar to the Commission's existing regulations governing requests for withholding, 10 CFR 2.790(c).

Proposed §§ 2.1020–.1028 are basically unchanged from their ACUS Model Rules counterparts, §§ 0.301–.310, except for certain conforming amendments. These provisions set forth the procedures that applicants should follow in submitting, and that the agency will follow in considering, requests for EAJA awards. A sentence has been added to proposed § 2.1025(a) to indicate that, absent a Commission designation of another official pursuant to proposed § 2.1006, the presiding officer with responsibility for the underlying proceeding will preside over the determination of any EAJA application. In addition, the time limits set for the answer, reply, and presiding officer's decision are slightly longer than those now allowed for comparable submissions in the course of a licensing hearing. Compare 10 CFR 2.705 (twenty days for answer), 2.706 (ten days for reply), and Part 2, App. A, ¶III(d) (thirty-five days for presiding officer's initial decision) with proposed 10 CFR 2.1021 (thirty days for answer to application), 2.1022 (fifteen days for reply), and 2.1026 (forty-five days for presiding officer's initial decision). The unique nature of the questions presented in determining whether an EAJA award should be made as well as the fact that the time expended in reaching such a determination will not impact on the operation of the facility involved in the underlying adversary adjudication makes such longer limitations acceptable. A further change is found in proposed § 2.1027, in that the provision of its ACUS Model Rules counterpart, § 0.308, providing for discretionary agency review of an initial EAJA award decision has been dropped as inconsistent with present NRC regulations that provide an appeal of right in agency adjudications. Also deleted is the final sentence of Model Rule § 0.308, which denotes those actions that may be taken by the reviewing body, and Model Rule § 0.309, which indicates that judicial review of a final agency decision on an EAJA application is available under 5 U.S.C. § 504(c)(2). Both of these provisions are considered unnecessary in light of existing regulations and the terms of the EAJA.

Finally, conforming amendments indicating the applicability of the Equal Access to Justice Act are proposed to be made to existing NRC regulations 10 CFR 1.12, which gives a general description of the Atomic Safety and Licensing Appeal Board's duties; 10 CFR 2.1, which defines the scope of the procedural rules found in Part 2; and 10 CFR 2.721 and 2.785, which respectively set forth the functions of the Atomic Safety and Licensing Board and the Atomic Safety and Licensing Appeal Board.

In accordance with 5 U.S.C. 553(d)(3), it is the Commission's intention to make these proposed rules immediately effective when they are published in final form. Good cause exists for such action in that the rules are procedural and, as such, will not adversely affect any member of the public.

III. Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission hereby certifies that this rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. A recent ACUS estimate based on the Uniform Caseload Accounting system indicates that the number of small entities involved will amount to perhaps one-half dozen per year. Moreover, the rule will have a beneficial effect for such entities by establishing a procedural framework for the submission and determination of applications for fees and expenses incurred in participating in NRC adversary adjudications.

IV. Paperwork Reduction Act

As required by the Paperwork Reduction Act of 1980, Pub. L. No. 96–511, 44 U.S.C. 3501–3520, this proposed rule has been submitted to the Office of Management and Budget (OMB) for clearance of its reporting/recordkeeping/application requirements. The SF–83, "Request for Clearance," a supporting statement, and other related documentation submitted to OMB have been placed in the NRC Public Document Room at 1717 H Street, NW., Washington, DC 20555 for inspection and copying for a fee.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and section 553 of title 5 of the United States Code, notice is hereby given that the following revisions to Title 10, Chapter 1, Parts 1 and 2, Code of Federal Regulations are contemplated:

PART 1—STATEMENT OF ORGANIZATION AND GENERAL INFORMATION

1. The authority citation for Part 1 is revised to read as follows:

Authority: Sec. 161, Pub. L. 83–703, 68 Stat. 948 (42 U.S.C. 2201); secs. 201, 203, 204, 205, and 209, Pub. L. 93–438, 88 Stat. 1242, 1244, 1245, 1246, and 1248 (42 U.S.C. 5841, 5843, 5844, and 5849); Pub. L. 94–79, 89 Stat. 413; and 5 U.S.C. 504, 552, and 553.

2. Section 1.12 of Part 1 is revised to read as follows:

§ 1.12 Atomic Safety and Licensing Appeal Panel.

The Atomic Safety and Licensing Appeal Panel is the organizational group from which Atomic Safety and Licensing Appeal Boards are selected. Under powers delegated by the Commission, these three-member Boards exercise the authority and perform the regulatory review functions which would otherwise be exercised and performed by the Commission. They perform these functions in proceedings on licenses under 10 CFR Part 50, and such other licensing proceedings as the Commission may specify, reviewing initial decisions and other issuances of Atomic Safety and Licensing Boards and other presiding officers. They shall also perform these functions in proceedings under the Equal Access to Justice Act. The Panel shall be comprised of a Chief Administrative Judge who shall be Chairman and such other Adminstrative Judges as may be appointed members of the Panel.

PART 2—RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEDURE

3. The authority citation for Part 2 is revised to read as follows:

Authority: Secs. 161p and 181, Pub.L. 83–703, 68 Stat. 950 and 953 (42 U.S.C. 2201(p) and 2231); sec. 191, as amended, Pub.L. 87–615, 76 Stat. 409 (42 U.S.C. 2241); sec. 201, as amended, Pub.L. 93–438, 88 Stat. 1242 (42 U.S.C. 5841); 5 U.S.C. 522; 5 U.S.C. 504; unless otherwise noted. Sections 2.200–2.206 also issued under sec. 186, Pub.L. 83–703, 68 Stat. 955 (42 U.S.C. 2236) and sec. 206, Pub.L. 93–438, 88 Stat. 1246 (43 U.S.C. 5846). Sections 2.800–2.808 also issued under 5 U.S.C. 553.

4. Section 2.1 of Part 2 is revised to read as follows:

§ 2.1 Scope.

This part governs the conduct of all proceedings, other than export and import licensing proceedings described in Part 110, under the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, for: (a) Granting, suspending, revoking, amending, or taking other action with respect to any license, construction permit, or application to transfer a license; (b) imposing civil penalties under section 234 of the Act; and (c) public rulemaking. This part also governs proceedings under the Equal Access to Justice Act.

5. In Part 2, section 2.721, paragraph (a) is revised to read as follows:

§ 2.721 Atomic safety and licensing boards.

(a) The Commission or the Chairman of the Atomic Safety and Licensing Board Panel may from time to time establish one or more atomic safety and licensing boards, each comprised of three members, one of whom will be qualified in the conduct of administrative proceedings and two of whom shall have such technical or other qualifications as the Commission or the Chairman of the Atomic Safety and Licensing Board Panel deems appropriate to the issues to be decided, to preside in such proceedings for granting, suspending, revoking, or amending licenses of authorizations as the Commission may designate, to preside in proceedings under the Equal Access to Justice Act as set forth in Subpart J of this Part, and to perform such other adjudicatory function as the Commission deems appropriate. The members of an atomic safety and licensing board shall be designated from the Atomic Safety and Licensing Board Panel established by the Commission.

* * * * *

6. In section 2.785, paragraph (a) is revised to read as follows:

§ 2.785 Functions of Atomic Safety and Licensing Appeal Board.

(a) The Commission has authorized Atomic Safety and Licensing Appeal Board to exercise the authority and perform the review functions which would otherwise have been exercised and performed by the Commssion, including, but not limited to, those under §§ 2.760–2.771, 2.912, and 2,913 in: (1) Proceedings on applications for licenses under Part 50 of this chapter, (2) such other licensing proceedings under the regulations in this chapter as the Commission may specify, and (3) proceedings under the Equal Access to Justice Act.

* * * * *

7. Part 2 is amended by adding a new Subpart J to read as follows:

Subpart J—Implementation of the Equal Access to Justice Act in Agency Proceedings

General Provisions

2.1000 Scope.
2.1001 Eligibility of applicants.
2.1002 Standards for awards.
2.1003 Allowable fees and expenses.
2.1004 Rulemaking on maximum rates for attorney or agent fees.
2.1005 Awards against other agencies.
2.1006 Delegations of authority.

Information Required From Applicants

2.1010 Contents of application.
2.1011 Net worth exhibit.
2.1012 Documentation of fees and expenses.
2.1013 When an application may be filed.

Procedures For Considering Applications

2.1020 Filing and service of documents.
2.1021 Answer to application.
2.1022 Reply
2.1023 Comments by other parties.
2.1024 Settlement.
2.1025 Further proceedings.
2.1026 Decision
2.1027 Agency review.

2.1028 Payment of award.

General Provisions

§ 2.1000 Scope.

The Equal Access to Justice Act (referred to as "the Act" in this subpart) provides for the award of attorney or agent fees and other expenses to eligible individuals and entities who are prevailing parties to adversary adjudications conducted by the NRC. Such adjudications are those held under 5 U.S.C. 554 in which the position of this or any other agency of the United States, or any component of an agency, is represented by an attorney or other representative who enters an appearance and participates in the proceeding. Proceedings to grant or renew licenses are excluded by the Act, but proceedings to modify, suspend, or revoke a license are covered if they are otherwise adversary adjudications within the meaning of the Act. If a proceeding includes matters covered by the Act and matters specifically excluded from coverage, any award made will include only fees and expenses related to covered issues.

§ 2.1001 Eligibility of applicants.

(a) To be eligible for an award of attorney fees and other expenses under the Act, the applicant must be a party to the adversary adjudication for which it seeks an award. The term "party" is defined in 5 U.S.C. 551(3). The applicant must show that it meets all conditions of eligibility set out in this section and in §§ 2.1010–.1013.

(b) Applicants eligible for awards under the Act are limited to:

(1) An individual with a net worth of not more $1 million;

(2) The sole owner of an unincorporated business who has a net worth of not more than $5 million, including both personal and business interests, and not more than 500 employees;

(3) A charitable or other tax-exempt organization described in section 501(c)(3) of the Internal Revenue Code (26 U.S.C. 501(c)(3)) with not more than 500 employees:

(4) A cooperative association as defined in section 15(a) of the Agriculture Marketing Act (12 U.S.C. 1141j(a)) with not more than 500 employees; and

(5) Any other partnership, corporation, association, or public or private organization with a net worth of not more than $5 million and not more than 500 employees.

(c) For the purpose of eligibility, the net worth and number of employees of an applicant shall be determined as of the date the proceeding was initiated.

(d) An applicant who owns an unicorporated business will be considered as an "individual" rather than a "sole owner of an unincorporated business" if the issues on which the applicant prevails are related primarily to personal interests rather than to business interests.

(e) The employees of an applicant include all persons who regularly perform services for remuneration for the applicant, under the applicant's direction and control. Part-time employees shall be included on a proportional basis (*e.g.*—two part-time employees each working one-half the time required of an average full-time employee should be counted as one full-time employee).

(f) The net worth and number of employees of the applicant and all of its affiliates must be aggregated to determine eligibility. Any individual, corporation, or other entity that directly or indirectly controls or owns a majority of the voting shares or other interest of the applicant, or any corporation or other entity of which the applicant directly or indirectly owns or controls a majority of the voting shares or other interest, will be considered an affiliate for purposes of this subpart, unless the presiding officer determines that such treatment would be unjust and contrary to the purposes of the Act in light of the actual relationship between the affiliated entities. In addition, the presiding officer may determine that financial relationships of the applicant other than those described in this paragraph constitute special circumstances that would make an award unjust.

(g) An applicant that participates in a proceeding primarily on behalf of one or more other persons or entities that would be ineligible is not itself eligible for an award.

§ 2.1002 Standards for awards.

(a) A prevailing applicant may receive an award for fees and expenses incurred in connection with a proceeding, or in a significant and discrete substantive portion of the proceeding, unless the position of the agency over which the applicant has prevailed was substantially justified. The burden of proof that an award should not be made to an eligible prevailing applicant is on the agency staff, which may avoid an award by showing that its position was reasonable in law and fact.

(b) An award will be reduced or denied if the applicant has unduly or unreasonably protracted the proceeding or if special circumstances make the award sought unjust.

§ 2.1003 Allowable fees and expenses.

(a) Awards will be based on rates customarily charged by persons engaged in the business of acting as attorneys, agents, and expert witnesses, even if the services were made available without charge or at a reduced rate to the applicant.

(b) No award for the fee of an attorney or agent under these rules may exceed $75 per hour. No award to compensate an expert witness may exceed the highest rate at which the NRC pays expert witnesses. An award may include the reasonable expenses of the attorney, agent, or witness as a separate item, if the attorney, agent, or witness ordinarily charges clients separately for these expenses.

(c) In determining the reasonableness of the fee sought for an attorney, agent, or expert witness, the presiding officer shall consider the following:

(1) If the attorney, agent, or witness is in private practice, his or her customary fee for similar services, or, if an employee of the applicant, the fully allocated cost of the services;

(2) The prevailing rate for similar services in the community in which the attorney, agent, or witness ordinarily performs services;

(3) The time actually spent in the representation of the applicant;

(4) The time reasonably spent in light of the difficulty or complexity of the issues in the proceeding; and

(5) Other factors as may bear on the value of the services provided.

(d) The reasonable cost of any study, analysis, engineering report, test, project, or similar matter prepared on behalf of a party may be awarded, to the extent that the charge for the service does not exceed the prevailing rate for similar services, and the study or other matter was necessay for preparation of the applicant's case.

§ 2.1004 Rulemaking on maximum rates for attorney or agent fees.

(a) If warranted by an increase in the cost of living or by special circumstances (such as limited availability of attorneys or agents qualified to handle certain types of proceedings), the NRC may adopt regulations providing that attorney or agent fees may be awarded at a rate higher that $75 per hour in some or all of the types of proceedings covered by this subpart. Any person may file with this agency a petition for rulemaking to increase the maximum rate for attorney or agent fees, in accordance with 10 CFR 2.802. The petition should identity the rate the petitioner believes this agency should establish and the types of proceedings in which the rate should be used. It should also explain fully the reasons why the higher rate is warranted.

§ 2.1005 Awards against other agencies.

If an applicant is entitled to an award because it prevails over another agency of the United States that participates in a proceeding before the NRC and takes a position that is not substantially justified, the award or an appropriate portion of the award must be made against that agency.

§ 2.1006 Delegations of authority.

The Commission delegates to the presiding officer and the Atomic Safety and Licensing Appeal Board authority to take final action on matters pertaining to the Equal Access to Justice Act, 5 U.S.C. 504, in adversary adjudications before these officials. The Commission may by order delegate authority to take final action on matters pertaining to the Equal Access to Justice Act in particular cases to other subordinate officials or bodies.

Information Required From Applicants

§ 2.1010 Contents of application.

(a) An application for an award of fees and expenses under the Act must identify the applicant and the proceeding for which an award is sought. The application must show that the applicant has prevailed and identify the position of an agency or agencies in the proceeding that the applicant alleges was not substantially justified. Unless the applicant is an individual, the application must also state the number of employees of the applicant and describe briefly the type and purpose of its organization or business.

(b) The application must also include a statement that the applicant's net worth does not exceed $1 million (if an individual) or $5 million (for all other applicants, including their affiliates). However, an applicant may omit this statement if:

(1) It attaches a copy of a ruling by the Internal Revenue Service that it qualifies as an organization described in section 501(c)(3) of the Internal Revenue Code (26 U.S.C. 501(c)(3)) or, in the case of a tax-exempt organization not required to obtain a ruling from the Internal Revenue Service on its exempt status, a statement that describes the basis for the applicant's belief that it qualifies under such section; or

(2) It states that it is a cooperative association as defined in section 15(a) of the Agricultural Marketing Act (12 U.S.C. 1141j(a)).

(c) The application must state the amount of fees and expenses for which an award is sought.

(d) The application may also include any other matters that the applicant wishes the NRC to consider in determining whether and in what amount an award should be made.

(e) The application must be signed by the applicant or an authorized officer or attorney of the applicant. It must also contain or be accompanied by a written verification under oath or under penalty of perjury that the information provided in the application is true and correct.

§ 2.1011 Net worth exhibit.

(a) Each applicant, except a qualified tax-exempt organization or cooperative association, shall provide with its application a detailed exhibit showing the net worth of the applicant and any affiliates (as defined in § 2.1001(f) of this subpart) when the proceeding was initiated. The exhibit may be in any form convenient to the applicant that provides full disclosure of the applicant's and its affiliates' assets and liabilities and is sufficient to determine whether the applicant qualifies under the standards in this subpart. The presiding officer may require an applicant to file additional information to determine its eligibility for an award.

(b) Ordinarily, the net worth exhibit is included in the public record of the proceeding. However, an applicant that objects to public disclosure of information in any portion of the exhibit and believes there are legal grounds for withholding it from disclosure may submit that portion of the exhibit directly to the presiding officer in a sealed envelope labeled "Confidential Financial Information," accompanied by a motion to withhold the information from public disclosure. The motion must describe the information sought to be withheld and explain, in detail, why it falls within one or more of the specific exemptions from mandatory disclosure under the Freedom of Information Act, 5 U.S.C. 552(b)(1)–(9), why public disclosure of the information would adversely affect the applicant, and why disclosure is not required in the public interest. The net worth material in question must be served on counsel representing the agency against which the applicant seeks an award, but need not be served on any other party to the proceeding. The motion to withhold the information shall be served on all parties to the proceeding, who shall have ten (10) days within which to file any reply supporting or contesting the request for nondisclosure. If the presiding officer finds that the information should not be withheld from disclosure, it must be placed in the public record of the proceeding, unless the applicant has indicated in its motion that, in the event of a refusal to withhold from disclosure, it would prefer that all net worth material be returned to it and that its award application be withdrawn. Otherwise, any request to inspect or copy the exhibit will be disposed of in accordance with the NRC's established procedures under the Freedom of Information Act, 10 CFR 9.3–.16.

§ 2.1012 Documentation of fees and expenses.

The application must be accompanied by full documentation of the fees and expenses, including the cost of any study, analysis, engineering report, test, project, or similar matter, for which an award is sought. A separate itemized statement must be submitted for each professional firm or individual whose services are covered by the application showing the hours spent in connection with the proceeding by each individual, a description of the specific services performed, the rate at which each fee has been computed, any expenses for which reimbursement is sought, the total amount claimed, and the total amount paid or payable by the applicant or by any other person or entity for the services provided. The presiding officer may require the applicant to provide vouchers, receipts, or other substantiation for any expenses claimed.

§ 2.1013 When an application may be filed.

(a) An application may be filed whenever the applicant has prevailed in the proceeding or in a significant and discrete substantive portion of the proceeding, but in no case later than thirty (30) days after a final disposition of the proceeding.

(b) If agency review or reconsideration is sought or taken of a decision as to which an applicant believes it has prevailed, proceedings for the award of fees will be stayed pending final disposition of the underlying controversy. If judicial review is sought or taken of a final disposition of the underlying controversy as to which an applicant believes it has prevailed, proceedings for the award of fees will be stayed and determined in accordance with 28 U.S.C. 2412(d)(3) and 5 U.S.C. 504(c)(1).

(c) For purposes of this subpart, final disposition means the later of (1) the date on which an initial decision or other disposition of the merits of the proceeding by the presiding officer, the Atomic Safety and Licensing Appeal Board, or the Commission becomes administratively final; (2) issuance of an order disposing of any petitions for reconsideration of a final order in the proceeding; (3) if no petition for reconsideration is filed, the last date on which such a petition could have been filed; or (4) issuance of a final order or any other final resolution of a proceeding, such as a settlement or voluntary dismissal, which is not subject to a petition for reconsideration.

Procedures For Considering Applications

§ 2.1020. Filing and service of documents.

Any application for an award or other pleading or document related to an application must be filed and served on all parties to the proceeding in accordance with the Commission's rules, 10 CFR 2.701 and 2.712, except as provided in § 2.1011(b) for confidential financial information.

§ 2.1021 Answer to application.

(a) Within thirty (30) days after service of an application, staff counsel may file an answer to the application. Unless staff counsel requests an extension of time for filing or files a statement of intent to negotiate under paragraph (b) of this section, failure to file an answer within the thirty-day period may be treated as a consent to the award requested.

(b) If staff counsel and the applicant believe that the issues in the fee application can be settled, they may jointly file a statement of their intent to negotiate a settlement. The filing of this statement extends the time for filing an answer for an additional thirty (30) days, and further extensions may be granted by the presiding officer upon request by staff counsel and the applicant.

(c) The answer must explain in detail any objections to the award requested and identify the facts relied on in support of staff counsel's position. If the answer is based on any alleged facts not already in the record of the proceeding, staff counsel shall include with the answer either supporting affidavits or a request for further proceedings under § 2.1025.

§ 2.1022 Reply.

Within fifteen (15) days after service of an answer, the applicant may file a reply. If the reply is based on any alleged facts not already in the record of the proceeding, the applicant shall include with the reply either supporting affidavits or a request for further proceeding under § 2.1025.

§ 2.1023 Comments by other parties.

Any party to a proceeding other than the applicant and staff counsel may file comments on an application within thirty (30) days after it is served or on an answer within fifteen (15) days after it is served. A commenting party may not participate further in proceedings on the application unless the presiding officer determines that the public interest requires its participation in order to permit full exploration of matters raised in the comments.

§ 2.1024 Settlement.

The applicant and staff counsel may agree on a proposed settlement of the award before final action on the application, either in connection with a settlement of the underlying proceeding, or after the underlying proceeding has been concluded. If a prevailing party and staff counsel agree on a proposed settlement of an award before an application has been filed, the application must be filed with the proposed settlement. Any settlement is subject to approval by the presiding officer. See 10 CFR 2.203.

§ 2.1025 Further proceedings.

(a) The presiding officer who renders the initial decision in the underlying proceeding will preside over any Equal Access to Justice Act proceeding unless the Commission designates some other official pursuant to § 2.1006. Ordinarily, the determination of an award will be made on the basis of the written record. However, on request of either the applicant or staff counsel, or *sua sponte*, the presiding officer may order further proceedings, such as an informal conference, oral argument, additional written submissions or an evidentiary hearing. Any further proceedings will be held only when necessary for full and fair resolution of the issues arising from the application, and must be conducted as promptly as possible.

(b) A request that the presiding officer order further proceedings under this section must specifically identify the information sought or the disputed issues and must explain why the additional proceedings are necessary to resolve the issues.

§ 2.1026 Decision.

The presiding officer's initial decision on the application should ordinarily be issued within forty-five (45) days after completion of proceedings on the application. The decision must include written findings and conclusions on the applicant's eligibility and status as a prevailing party, and an explanation of the reasons for any difference between the amount requested and the amount awarded. The decision must also include, if at issue, findings on whether the agency's position was substantially justified, whether the applicant unduly protracted the proceedings, or whether special circumstances make an award unjust. If the applicant has sought an award against more than one agency, the decision must allocate responsibility for payment of any award made among the agencies, and must explain the reasons for the allocation made.

§ 2.1027 Agency review.

Review of the initial decision on the fee application shall be requested and conducted in accordance with §§ 2.760, 2.762–.763, 2.770–.772, and 2.785–.787. If neither the applicant nor staff counsel seeks review and neither the Atomic Safety and Licensing Appeal Board nor the Commission takes review on its own initiative, the initial decision on the application becomes a final decision of the agency thirty (30) days after it is issued.

§ 2.1028 Payment of award.

An applicant seeking payment of an award from the NRC shall submit a copy of the agency's final decision granting the award, accompanied by a statement that the applicant will not seek review of the decision in the United States courts to Director, Division of Accounting, Office of the Controller, U.S. Nuclear Regulatory Commission, Washington, DC, 20555. The agency will pay the amount awarded to the applicant within sixty (60) days, unless judicial review of the award or of the underlying decision of the adversary adjudication has been sought by the applicant or any other party to the proceeding.

Dated at Washington, DC, this 23d day of October 1981.

For the Commission.

Samuel J. Chilk,

Secretary of the Commission.

➢47 FR 47260
Published 10/25/82
Comments must be submitted on or before 11/24/82. Comments received after this date will be considered if it is practical to do so.

10 CFR Part 2

Commission Review Procedures for Power Reactor Construction Permits; Immediate Effectiveness Rule

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission is proposing to amend its rules of practice for review of Atomic Safety and Licensing Board decisions

granting power reactor construction permits. Under the proposed amendment, the Commission would itself conduct a limited review of the Licensing Board decision to determine whether it should go into effect so as to authorize the issuance of the construction permit pending the completion of administrative appeals. The requirement that the Appeal Board conduct a similar effectiveness review would be deleted. This proposal is intended to avoid unnecessary delay in the issuance of construction permits. It conforms the effectiveness review procedures for construction permits and construction authorizations (e.g., limited work authorizations) with those presently in effect for operating licenses and is based partly upon Commission experience in reviewing operating license decisions. It would not affect the separate Appeal Board and Commission appellate reviews of the merits of Licensing Board decisions.

DATE: Comments must be submitted on or before November 24, 1982. Coments received after this date will be considered if it is practical to do so.

ADDRESS: Comments may be mailed to the Secretary, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555; Attention: Docketing and Service Branch. Copies of comments received may be examined in the Commission's Public Document Room at 1717 H Street, NW., Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Richard A. Parrish, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone: (202) 634–3224.

SUPPLEMENTARY INFORMATION: In the aftermath of the accident at Three Mile Island (TMI), the Nuclear Regulatory Commission suspended in part its so-called immediate effectiveness rule. The original rule authorized the Director of Nuclear Reactor Regulation to issue construction permits, operating licenses, or amendments thereto immediately upon receipt of favorable Licensing Board decisions, notwithstanding the filing of administrative appeals. 10 CFR 2.764(a) (1981 ed.). In its place, a special review procedure was adopted to provide that no decision authorizing issuance of a nuclear power reactor construction permit, construction authorization (e.g., limited work authorization) or operating license could become effective, and no permit or license thereby issued, without prior Appeal Board and Commission review. See 44 FR 65049, published November 9, 1979. 10 CFR Part 2, Appendix B (1981 ed.).

The rule as applied to operating license decisions has since been partially reinstated. 10 CFR 2.764(f) (1982 ed.). See 46 FR 28627, published May 28, 1981; 46 FR 47764, published September 30, 1981. The new procedures exempted decisions authorizing fuel loading and low-power testing from the effectiveness review, provided a 10-day comment period on full-power decisions, and removed the Appeal Board from the effectiveness review while expanding the time set as a goal for Commission review from twenty (20) to thirty (30) days. These modifications were based on experience gained in reviewing several operating license decisions and the determination that TMI-related rerquirements were sufficiently settled to warrant the amended procedures. Stays of effectiveness remain available pursuant to 10 CFR 2.788 and the appellate review of the merits of Licensing Board decisions was retained.

The application of the immediate effectiveness rule to contruction permit decisions has been under review by the Commission for quite some time. 44 FR 33883, published June 13, 1979; 45 FR 34279, published May 22, 1980. In a 1978 Seabrook decision, *Public Service Company of New Hampshire* (Seabrook Station, Units 1 and 2), 7 NRC 1 (1978), the Commission had requested a detailed study of the rule and options for modifying it. See "Report of the Advisory Committee on Construction During Adjudication" (Milhollin Report), NUREG–0646, January 1980. The Commission is now considering modifying the rule as it applies to construction permits and construction authorizations (e.g., limited work authorizations) to provide a 10-day comment period on construction permit decisions, remove the Appeal Board from the effectiveness review process, and establish a thirty (30) day goal for the completion of Commission's effectiveness review. This proposal is based on experience gained in the Commission review of operating license decisions, as no construction permits have been issued since the suspension of the original rule. A more detailed explanation of the backgound, purpose, and effect of this rule may be found in the notices cited above. The Commission intends to retain the option of further modifying the rule in accordance with the alternatives presented in the Milhollin Report and those notices.

Part 2 of the Commission's rules, which includes § 2.764 on Immediate Effectiveness, will be the subject of reform proposals from the Commission's Regulatory Reform Task Force later this year. The rules proposed here are intended only to put the effectiveness review procedures for construction permits and limited work authorizations on a par with operating licenses and are not intended as a comprehensive revision of immediate effectiveness procedures. Such revisions, if and when they are proposed, would come at a later date as part of broader reforms to the Commission's hearing process.

This proposed rule would not affect the standard Appeal Board and Commission appellate reviews of the merits of Licensing Board decisions, or the availability of stays pursuant to 10 CFR 2.788. The Commission wishes to emphasize that the proposed modifications are not intended to allow any reduction in the overall quality of NRC adjudicatory proceedings. The changes, if adopted, would be applicable to ongoing NRC construction permit proceedings.

The Commission notes that the proposed rule retains the provision that TMI-related requirements that extend beyond NRC regulations may be imposed on applicants for operating licenses. TMI-related requirements for construction permit applications have been finalized as Commission regulations. See 47 FR 2286, published January 15, 1982.

Commissioner Ahearne's Dissenting Views

I was willing to maintain the status quo. Addressing immediate effectiveness of Licensing Board decisions for construction permits should involve a substantial discussion. Because of the limited number of outstanding construction permit applications, such a discussion would have limited significance for the near term. At the same time, major changes to the licensing process are being discussed, which in turn will affect considerations underlying immediate effectiveness. Consequently, I was willing to defer consideration of the issue. However, the Commission chose to take up the matter at this time.

In a 1978 *Seabrook* opinion the Commission pointed out that "our rule giving immediate effectiveness to our Licensing Board's grant of a construction permit and our stay rule often operate together to assure that Commission-level review will not take place until such time as construction is well underway. This case illustrates the need to develop a procedure for assuring early Commission-level review of controverted licensing proceedings, where appropriate, particularly where siting is an issue." *Public Service Company of New Hampshire* (Seabrook

Station, Units 1 and 2), CLI–78–1, 7 NRC 1, 6–7 (1978) (footnote omitted). In that opinion the Commission announced it was going to initiate a study to assess the issues. In January 1979, the Commission established a committee to conduct the study; and in December 1979, the committee submitted its final report to the Commission (often referred to as the "Milhollin study").

As a separate matter, as a result of the Three Mile Island accident, in October 1979 the Commission issued a formal statement that new construction permits (as well as limited work authorizations and operating licenses) "shall be issued only after action of the Commission itself." The current version of the regulations was adopted in November 1979 to implement that decision.

After consideration of the Milhollin study, the Commission issued a notice of proposed rulemaking in May 1980 in order to obtain comment on the three options for altering the Commission's immediate effectiveness rule discussed by the committee. In March 1981, the Office of General Counsel prepared a paper proposing the Commission once again address the issues raised in *Seabrook* and the proposals suggested by the Milhollin study. In connection with that paper OGC was asked to prepare the current proposal.

I am not concurring because I do not believe the Commission has addressed the concerns identified in *Seabrook* or given the Milhollin study the full consideration it deserves.

Paperwork Reduction Act Statement

This proposed rule contains no new or amended recordkeeping, reporting, or application requirement or any type of information collection requirement subject to the Paperwork Reduction Act (Pub. L. 96–511).

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission hereby certifies this rule, if adopted, will not have a significant economic impact on a substantial number of small entities. This proposed rule would affect the Commission's Rules of Practice and Procedures by permitting expedition of the adjudicatory process.

List of Subjects in 10 CFR Part 2

Administrative practice and procedure, Antitrust, Byproduct material, Classified information, Environmental protection, Nuclear materials, Nuclear power plants and reactors, Penalty, Sex discrimination, Source material, Special nuclear material, Waste treatment and disposal.

PART 2—RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and section 553 of Title 5 of the United States Code, notice is hereby given that adoption of the following amendments to 10 CFR Part 2 is contemplated.

1. The authority citation for Part 2 reads as follows:

Authority: Secs. 161, 181, 68 Stat. 948, 953 (42 U.S.C. 2201, 2231); sec. 191, as amended, Pub. L. 87–615, 76 Stat. 409 (42 U.S.C. 2241); sec. 201, Pub. L. 93–438, 88 Stat. 1242, as amended by Pub. L. 94–79, 89 Stat. 413 (42 U.S.C. 5841); 5 U.S.C. 552. (Section 2.101 also issued under secs. 53, 62, 81, 103, 104, 105, 68 Stat. 930, 932, 935, 936, 937, 938, as amended (42 U.S.C. 2073, 2093, 2111, 2133, 2134, 2135); sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332); sec. 301, 88 Stat. 1248 (42 U.S.C. 5871). Sections 2.102, 2.104, 2.105, 2.721 also issued under secs. 102, 103, 104, 105, 183, 189, 68 Stat. 936, 937, 938, 954, 955, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2233, 2239). Sections 2.200–2.206 also issued under sec. 186, 68 Stat. 955 (42 U.S.C. 2236); sec. 206, 88 Stat. 1246 (42 U.S.C. 5846). Sections 2.600–2.606, 2.730, 2.772 also issued under sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332). Sections 2.700a, 2.719 also issued under 5 U.S.C. 554. Sections 2.754, 2.760, 2.770 also issued under 5 U.S.C. 557. Section 2.790 also issued under sec. 103, 68 Stat. 936, as amended (42 U.S.C. 2133). Sections 2.800–2.807 also issued under 5 U.S.C. 553. Section 2.808 also issued under 5 U.S.C. 553 and sec. 102, 83 Stat. 853 (42 U.S.C. 4332). Section 2.809 also issued under 5 U.S.C. 553 and sec. 29, Pub. L. 85–256, 71 Stat. 579, as amended by Pub. L. 95–209, 91 Stat. 1483 (42 U.S.C. 2039). Appendix A is also issued under sec. 6, Pub. L. 91–580, 84 Stat. 1472 (42 U.S.C. 2135).)

§ 2.764 [Amended]

2. In both paragraphs (a) and (b) of § 2.764, the opening phrase "Except as provided in paragraphs (c) through (f) of this section," is amended to read "Except as provided in paragraphs (c) through (e) of this section,".

3. Paragraphs (e) (1) and (2) of § 2.764 are revised to read as follows:

* * * * *

(e) *Nuclear Power Reactor Construction Permits and Operating Licenses.* (1) *Atomic Safety and Licensing Boards.*—(i) Atomic Safety and Licensing Boards shall hear and decide all issues that come before them, indicating in their decisions the type of licensing action, if any, which their decision would authorize. A Board's decision authorizing issuance of a construction permit, a construction authorization (e.g., limited work authorization), or an operating license (other than a fuel loading and low-power (up to 5 percent of rated power) testing license) shall not become effective until the Commission actions outlined in paragraph (e)(2) of this section have taken place. Insofar as it authorizes fuel loading and low-power operation up to 5 percent, the Board's decision shall become effective immediately and the Director shall issue the appropriate permit or license in accordance with paragraph (b) of this section.

(ii) In reaching their decisions, the Boards should interpret existing regulations and regulatory policies with due consideration to the implications for those regulations and policies of the Three Mile Island accident. In this regard, it should be understood that as a result of analyses still under way, the Commission may change its present regulations and regulatory policies regarding operating licenses in important respects. Thus, compliance with existing regulations may turn out to no longer warrant approval of an operating license application. As provided in paragraph (e)(2) of this section, in addition to taking generic rulemaking actions, the Commission will be providing case-by-case guidance on changes in regulatory policies in conducting its reviews in adjudicatory proceedings. The Boards shall, in turn, apply these revised regulations and policies in cases then pending before them to the extent that they are applicable. The Commission expects the Licensing Boards to pay particular attention in their decisions to analyzing the evidence on those safety and environmental issues arising under applicable Commission regulations and policies which the Boards believe present serious, close questions and which the Boards believe may be crucial to whether a permit or license should become effective before full appellate review is completed. Furthermore, the Boards should identify any aspects of the case which in their judgment present issues on which prompt Commission policy guidance is called for. The Boards may request the assistance of the parties in identifying such policy issues but, absent specific Commission directive, such policy issues shall not be the subject of discovery, examination, or cross-examination.

(2) *Commission.* (i) Reserving the power to step in at an earlier time, the Commission will, upon receipt of the Licensing Board decision authorizing issuance of a construction permit, a construction authorizing (e.g., limited work authorization) or an operating license, other than a decision authorizing only fuel loading and low-power (up to 5 percent of rated power) testing, review the matter on its own motion to determine whether to stay the effectiveness of the decision. A construction authorization (e.g., limited work authorization) construction permit, or operating license decision will be stayed by the Commission if it determines that it is in the public interest to do so, based on a consideration of the gravity of the substantive issue, the likelihood that it has been resolved incorrectly below, the degree to which correct resolution of the issue would be prejudiced by construction or operation pending review, and other relevant public interest factors.

(ii) For decisions subject to this review and consistent with the target schedule set forth in this section, the parties may file brief comments with the Commission pointing out matters which, in their view, pertain to the immediate effectiveness issue. To be considered, such comments must be received within 10 days of the Board decision. However, the Commission may dispense with comments by so advising the parties, No extensive stay shall be issued without giving the affected parties an opportunity to be heard.

(iii) The Commission intends to issue a stay decision within 30 days of receipt of the Licensing Board's decision. The Licensing Board's initial decision will be considered stayed pending the Commission's decision insofar as it may authorize construction or operations other than fuel loading and low-power (up to 5 percent of rated power) testing.

(iv) In announcing a stay decision, the Commission may allow the proceeding to run its ordinary course or give instructions as to the future handling of the proceeding (for example, it may direct the Appeal Board to review the merits of particular issues in expedited fashion; furnish policy guidance with respect to particular issues; or decide to review the merits of particular issues itself, bypassing the Appeal Board). Furthermore, the Commission may in a particular operating license case determine that compliance with existing regulations and policies may no longer be sufficient to warrant approval of an operating license application and may alter those regulations and policies.

* * * * *

4. Paragraph (f) of § 2.764 is removed.

5. Paragraph (g) of § 2.764 is redesignated as paragraph (f).

Dated at Washington, D.C., this 19th day of October, 1982.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,
Secretary of the Commission.

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48 FR 50550
Published 11/2/83
Comment period expires 12/2/83
≫ **Comment period extended to 1/3/84.**

10 CFR Part 2

Rules of Practice for Domestic Licensing Proceedings; Role of NRC Staff in Adjudicatory Licensing Hearings

AGENCY: Nuclear Regulatory Commission.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Nuclear Regulatory Commission is considering amending its rules of practice to change the NRC staff's role as a full party in administrative adjudicatory hearings in initial licensing proceedings for nuclear power reactors. This advance notice of proposed rulemaking is being issued to invite advice and recommendations on several proposals which are under active consideration and on a series of related questions to help the NRC decide whether and to what extent changes should be made in the NRC staff's present role. The proposals described in this notice may change in light of the comments received.

DATES: The comment period expires December 2, 1983. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

ADDRESSES: Send written comments or suggestions to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch. Copies of comments received by the Commission may be examined at the NRC Public Document Room, 1717 H Street, NW., Washington, D.C. 20555.

FOR FURTHER INFORMATION CONTACT: Linda S. Gilbert, Office of the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Telephone: (301) 492-7678.

SUPPLEMENTARY INFORMATION:

Background

In November 1981, a Regulatory Reform Task Force composed of senior NRC Personnel was established to review the reactor licensing process of the Nuclear Regulatory Commission. Instructed to develop and make recommendations to the Commission on possible actions, administrative as well as legislative, which could be taken to improve the effectiveness of the licensing process in both the near term and over the longer range, the Regulatory Reform Task Force was asked to consider the following objectives:

—To create a more effective and effective vehicle for raising and resolving legitimate public safety and environmental issues regarding the applications under review,

—To develop means for more effective future use of NRC resources in the licensing of new plants,

—To avoid regulatory uncertainty and placing unjustifiable economic burdens on utilities that may wish to build a nuclear plant (and their rate payers),

—To accomplish the above without impairing protection of public health and safety.

An extensive review system to consider the recommendations of the Regulatory Reform Task Force was also devised. In November 1981, chairman Palladino appointed a Senior Advisory Group to assist him in reviewing materials presented by the Task Force. In March 1982, an Ad Hoc Committee for Review of Nuclear Reactor Licensing Proposals, made up of representatives from industry, public interest groups and state governments, was formed. The review process called for the recommendations of the Task Force to be presented first to the Senior Advisory Group and then to the Commission. After presentation to the Commission, the recommendations were to be forwarded to the Ad Hoc Committee so that its members could review the recommendations and submit a report to the Commission. After the Ad Hoc Committee filed its report, the Commission would determine a course of action.

Since November 3, 1982, when the Regulatory Reform Task Force submitted its draft report [1] to the Commission, the Commission has been meeting periodically to consider the topics covered by the draft report. The Ad Hoc Committee recently filed its final report on the administrative reform proposal. On July 13, 1983, the Commission held a public meeting to discuss a proposal, outlined in Chapter 6 of Part I of the Task Force draft report, to amend Commission policy on participation of NRC staff in initial licensing proceedings. The Commission decided to publish this advance notice of proposed rulemaking outlining its concerns, describing in general terms several possible approaches which are under active consideration, and inviting suggestions and public comments. Following review and analysis of the responses received, the Commission will determine whether and to what extent the NRC staff's present role as an advocate in initial licensing proceedings should be changed and the manner in which its Rules of Practice should be revised.

The Role of the NRC Staff in Adjudicatory Licensing Hearings and the Need for Change

In a proceeding for the issuance of a permit to construct or a license to operate a nuclear power reactor, the license applicant has the burden of showing that it can contruct and operate the plant safely. During the course of the licensing proceeding, an intervenor may challenge the applicant. The NRC staff has no stake in the issuance of the license, a circumstance which has led some persons to conclude that there is no need for NRC staff participation in a licensing hearing. However, the Commission relies heavily on the staff's special expertise in determining whether the applicant has met the requirements for issuance of a license and what conditions the license should contain.

The type of hearing used in NRC licensing proceedings is adversarial in nature and requires that all parties, including the NRC staff, advocate specific positions on a variety of issues. The NRC staff makes every effort to address each issue in a fair and objective manner to ensure that the radiological health and safety of the public will be adequately protected. When the staff's participation in the hearing process lends support to the case in favor of the application, however, an impression is created among some members of the public that the NRC staff is advocating the applicant's case. As a consequence, the credibility of the Commission as an impartial and objective regulatory agency has been questioned. This perception of partiality has contributed to an erosion of public confidence in the safety of nuclear power plants.

Under the Atomic Energy Act of 1954, as amended, the function of the Nuclear Regulatory Commission and its staff is to protect the radiological health and safety of the public. In carrying out its duties as a full party in a contested licensing proceeding, the NRC staff must satisfy this statutory obligation to represent and protect the public interest. In view of the importance and highly technical nature of the safety issues which must be considered in determining whether, or under what conditions, to license a nuclear power plant, the Commission is concerned whether participation by the NRC staff as an advocate in individual licensing proceedings, is the most effective method of achieving this objective. It is conceivable that the interest of the public in securing adequate radiological health and safety protection might be better served, and the expertise of the NRC staff better used, it staff resources now committed to litigating admitted contentions in individual licensing proceeding were reduced and more staff resources were made available for the study, analysis and resolution of other important noncontested matters involved in particular proceedings and generic safety questions common to one or more classes of light water reactors. A separate, but related, concern is whether limiting the participation of the NRC staff in individual licensing proceedings will mitigate in any meaningful way the legal constraints placed on the Commission's access to and use of NRC staff expertise by the separation of functions requirements of the Administrative Procedure Act.[2]

Proposals Under Consideration

The Commission is actively considering several proposals for restructuring the role of the NRC staff in formal administrative adjudications[3] in contested initial licensing proceedings.

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[1] SECY-82-447, November 3, 1982, transmitting the draft report of the Regulatory Reform Task Force to the Commission for appropriate action. This document has been placed in the Commission's Public Document Room at 1717 H Street, NW., Washington, D.C. 20555, where it is available for inspection and copying for a fee.

[2] 5 U.S.C. 554(d) states: "The employee who presides at the reception of evidence pursuant to section 556 of this title shall make the recommended decision or initial decision required by section 557 of this title, unless he becomes unavailable to the agency. Except to the extent required for the disposition of ex parte matters as authorized by law, such an employee may not—

(1) Consult a person or party on a fact in issue, unless on notice and opportunity for all parties to participate; or

(2) Be responsible to or subject to the supervision or direction of an employee or agent engaged in the performance of investigative of prosecuting functions for an agency.

An employee or agent engaged in the performance of investigative or prosecuting functions for an agency in a case may not, in that or a factually related case, participate or advise in the decision, recommended decision, or agency review pursuant to section 557 of this title, except as witness or counsel in public proceedings. This subsection does not apply—

(A) In determining applications for initial licenses;

(B) To proceedings involving the validity or application of rates, facilities, or practices of public utilities or carriers; or

(C) To the agency or a member or members of the body comprising the agency."

[3] The Nuclear Regulatory Commission and its predecessor agency, the Atomic Energy Commission, have consistently taken the position that reactor licensing proceedings, which are subject to the hearing provisions of section 189a. of the Atomic Energy Act of 1954, as amended, are on-the-record adjudications under the applicable provisions of the Administrative Procedure Act (5 U.S.C. 554, 556 and 557).

Option 1

The first proposal would alter the NRC staff's current role as a full party in all formal licensing adjudications by limiting staff participation as a party in contested initial licensing proceedings to those controverted factual issues on which it disagrees with the technical bases, rationale or conclusions of the license applicant or other parties in the proceeding. This proposal would also permit the staff to act as an *amicus* in these proceedings. As an *amicus*, the staff would be able to advise presiding officers on the record regarding any other matter in the proceeding, either on its own initiative or upon request of the presiding officer. The proposal would not change the NRC staff's role as a full party in other types of proceedings, such as enforcement matters.

Under Option 1, the staff would become a party to contested proceedings involving initial licensing on a discretionary basis. If the staff disagrees with a party's technical basis, rationale or conclusions, the staff could provide notice to the parties and introduce evidence at the hearing articulating its position and its basis for disagreement. In this way, the staff would become a party to the proceeding, but only with respect to the particular issue(s) on which it elected to participate. Other parties would have an opportunity to rebut the staff's evidence. Cross-examination by and of the staff would also be permitted to the extent otherwise allowed by the Commission's Rules of Practice.

With respect to Option 1, several points should be emphasized. First, Option 1 would apply only to initial licensing proceedings. Initial licensing would include any formal proceeding on an application for a construction permit, operating license, or any other license for a facility or other activity, including any amendment or modification. Normally excluded from initial licensing would be proceedings involving the renewal, revocation, suspension, annulment, withdrawal or agency-initiated modification of licenses. Thus, under Option 1, the staff would remain a full party in all agency enforcement actions and in all license renewal and withdrawal proceedings.

Second, Option 1 would permit discretionary participation by the staff on one or more issues in a proceeding. There may be instances where the public interest would be better served through staff participation as a party. For example, the staff may take exception to a methodology, analysis or conclusion of a party and, therefore, may find it necessary to function as a formal party on selected issues in order to fully develop the record. The frequency of staff participation as a party in such instances would depend on the standards chosen to govern such participation. Within that constraint, this provision would give the staff the flexibility to carry out the agency mission as circumstances may require.

Third, under Option 1 the staff would become a party to the proceeding only with respect to the particular issue(s) on which it elected to participate. Thus, while the staff would submit evidence, file proposed findings of fact, take appeals, and otherwise exercise party rights on matters relating to those elected issues, the staff would not participate on other matters, except to a limited extent as an *amicus*.

In addition to permitting the staff to become a party to an initial licensing proceeding on a particular issue, Option 1 would permit the staff to participate in the proceeding to a limited extent as an *amicus*. In this capacity, the staff could provide on-the-record advice "on any matter in the proceeding" to the presiding officer, either on its own initiative or at the request of the presiding officer. The staff and presiding officers would have great flexibility in providing or requesting advice. The only exception would be that such advice could not be requested or provided concerning issues on which the staff was already participating as a party because of a disagreement with the license applicant or other party.

While *amicus* advice on any procedural or substantive matter pending before a presiding officer would be permitted, such advice would not necessarily be offered or solicited routinely. The Commission could direct that the *amicus* mechanism be used sparingly for unusal, important or complex questions in which the staff perspective could be of significant benefit to the presiding officer. For example, a presiding officer may wish to request staff views on the merits of a motion for summary disposition which concerns a key issue in a proceeding, or the staff may wish to provide its views to a presiding officer when it believes that a particular procedural request or substantive issue may have significant implications for other proceedings or invites an unwarranted departure from past practice. Formal cross-examination of staff members could be provided, or the parties to the proceeding could be given a reasonable opportunity to comment on the staff's views.

Under Option 1, the staff would continue to be served with all documents filed in the proceeding, regardless of whether the staff participates as a party or acts as an *amicus*. However, the Commission's formal procedural rules governing the staff's participation, including the deposition of named NRC employees and the answering of interrogatories by NRC personnel, could be used to reach the staff concerning only those issues on which the staff participates as a party. Any ACRS report, safety evaluation report or environmental impact statement relating to the proceeding might be deemed to be admitted as part of the hearing record of the proceeding without the formality of being offered into evidence by the NRC staff. Or, the staff could be required to respond to discovery requests on these documents, and to provide witnesses to sponsor the documents and to respond to cross-examination.

Option 2

Like Option 1, Option 2 would apply only to initial licensing proceedings. The staff would remain a full party in all agency enforcement actions and in all license renewal and withdrawal proceedings. Under Option 2, however, the role of the NRC staff in initial licensing proceedings would be structured somewhat differently in order to permit the staff to carry out its primary function in those proceedings; namely, to assist in the development of a full and balanced record. In this way, the staff would help the Licensing Board

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Section 189a.(1) of the Atomic Energy Act of 1954, as amended, provides: "In any proceeding under this Act, for the granting, suspending, revoking, or amending of any license or construction permit, or application to transfer control, and in any proceeding for the issuance or modification of rules and regulations dealing with the activities of licensees, and in any proceeding for the payment of compensation, an award, or royalties under sections 153, 157, 186c., or 188, the Commission shall grant a hearing upon the request of any person whose interest may be affected by the proceeding, and shall admit any such person as a party to such proceeding. The Commission shall hold a hearing after thirty days' notice and publication once in the **Federal Register**, on each application under section 103 or 104b. for a construction permit for a facility, and on any application under section 104c. for a construction permit for a testing facility. In cases where such a construction permit has been issued following the holding of such a hearing, the Commission may, in the absense of a request therefor by any person whose interest may be affected, issue an operating license or an amendment to a construction permit or an amendment to an operating license without a hearing, but upon thirty days' notice and publication once in the **Federal Register** of its intent to do so. The Commission may dispense with such thirty days' notice and publication with respect to any application for an amendment to a construction permit or an amendment to an operating license upon a determination by the Commission that the amendment involves no significant hazards consideration."

and the Commission to make a sound determination in the case—the kind of determination that would foster greater public confidence in the level of protection provided with respect to radiological health and safety matters.

In order to accomplish these objectives, the NRC staff would cease to function as an advocate in initial licensing proceedings. Under Option 2, the NRC staff would not be involved in the resolution of any procedural matters, including, for example, such matters as the standing of persons to participate in the proceeding, qualifications of witnesses and the relevance of testimony. Nor would the NRC staff be involved in the selection and formulation of contentions or in the preparation of proposed findings of fact or conclusions of law.

Once the contentions have been formulated and the issues joined in a particular proceeding, however, the NRC staff would be required to supply views and analyses for the record on every substantive issue raised. Neither the staff nor the Licensing Board would have any discretion in selecting issues on which the staff would present evidence. All substantive issues to be considered in the hearing would have to be addressed. The NRC staff would be required to respond to discovery requests, would be subject to cross-examination and would be permitted to cross-examine witnesses of other parties who challeged the staff's analyses. Although the NRC staff would be permitted to submit views respecting possible license conditions, it would be precluded from providing formal findings of fact and conclusions of law. Instead, the applicant and the intervenor, as the parties in dispute, would be responsible for preparing proposed findings of fact and conclusions of law. Responsibility for summarizing the record in the proceeding and for making the requisite factual findings and legal conclusions to support the decision reached would rest in each case with the Licensing Board.

Option 3

Option 3 would be to retain the staff's existing role in the licensing process. The staff would continue to function as a full party advocate on all aspects of initial licensing proceedings. This option could be implemented without any modification of existing practice. Alternatively, it could be coupled with measures designed to improve public perception of the staff's role (as, for example, in Option 4 below) or to allow greater Commission access to staff expertise, consistent with applicable law.

Option 4

Option would involve expanded public involvement in initial licensing proceedings before a notice of opportunity for hearing is issued. This option could be used in combination with any of the first three options. It would require that, whenever the applicant and staff met to discuss various aspects of the license application and to resolve their differences, notice of the meeting would be provided and interested persons would be permitted to attend. Meetings would be held in places convenient for interested members of the public; *i.e.*, near the proposed plant site rather than at Commission headquarters. Interested persons would be permitted to identify and discuss issues of particular concern regarding the application and to ask questions of the applicant and staff. Thereafter, the staff would address those questions and concerns in a section of its Safety Evaluation Report, much as it now discusses comments received on its environmental analaysis in the Environmental Impact Statement.

This option would allow interested members of the public to observe the staff's initial review of the application and to contribute to the process of negotiating with the applicant for various changes that may be considered desirable. It would likely contribute to increased public understanding of the staff's role. It could also provide useful information about local and site-related concerns in a non-adversarial setting.

Questions and Concerns

In its preliminary consideration of the role of the NRC staff in initial licensing hearings, the Commission has identified several matters relating to the NRC staff's responsibility to the public and to the basic fairness and integrity of the licensing proceeding which it believes warrant careful study and should be taken into consideration in assessing the strengths and weaknesses of any specific proposal. Advice and recommendations on the relevance and relative importance of these matters and on any other points considered pertinent are invited from all interested persons. comments and supporting reasons are also requested on the extent to which Options 1 and 2, or any suggested alternative proposal, might provide a constructive response to these concerns. Responses to the following questions are particularly requested.

General

1. What should be the role of the NRC staff in initial licensing proceedings? Why?

2. Should the staff present its views on all aspects of the proceeding?

a. Does the staff have a public obligation to do so?

b. Is the staff's participation necessary to develop a sound record for decisionmaking?

3. What role for the NRC staff would make the most effective use of staff resources?

4. What do commenters believe is the public's perception of the staff's role in the licensing process? Would any of the proposed options help to improve that perception?

5. Would changes in the staff's role be useful in alleviating legal constraints on the Commission's access to staff expertise on contested issues?

Option 1

1. Should the staff be accorded the discretion to choose those substantive issues on which it will participate in initial licensing proceedings?

a. What criteria should the staff use in determining on which issues it will participate?

b. If the staff does not choose to participate, what would be the status of staff-prepared documents in those proceedings—for example, the SER and the EIS? Should the staff's licensing review documents be treated as evidence and always entered into the record of the proceeding? Should the staff have to provide witnesses to sponsor those documents? Should parties be permitted to examine those witnesses? Should parties be able to obtain discovery on information covered in those documents?

c. To what extent and under what conditions should discovery be permitted against the staff?

d. Should members of the staff serve as witnesses in the hearing—either as Board witnesses or as witnesses for a party?

e. If the Commission consults staff members concerning contested issues on which the staff is not a "party", what legal constraints would there be on the relationship of those staff members to the parties? to other staff members? to the Licensing Board?

2. Should the staff serve as an informal or formal advisor to the licensing board on contested issues on which it does not participate as a party?

a. How formal should the staff's participation be? Should staff members serve as board witnesses? Should they provide their advice in writing?

b. Should parties be able to question or dispute that advice? obtain discovery on it? cross-examine staff witnesses?

c. If the staff advises the licensing board, are there any legal constraints on the relationship of those staff members to the parties? to the Commission? to other staff members?

3.What should be the staff's role on appeal?

Option 2

1. If the staff remains a party in initial licensing proceedings, should it take a position on procedural issues?

a. Should the staff be given the discretion to choose on which procedural issues it will provide views?

b. Should the Commission establish criteria to guide the staff on when to participate on procedural issues? What should they be?

c. Should the staff participate in the formulation of contentions?

d. Should the staff be required to file proposed findings of fact and conclusions of law?

2. What should be the staff's role on appeal?

Option 3

1. Can steps be taken to improve the public's perception of the staff's role in licensing proceedings without altering the staff's existing role as an advocate?

Option 4

1. Should the Commission provide an opportunity for greater public involvement in the early states of licensing proceedings?

2. How might that approach affect public perception and acceptance of the staff's role? negotiations between the applicant and staff concerning the application? resolution of contested aspects of the application?

Availability of Reference Documents

In recent years, several studies and reports have been written, both within and outside NRC, re-examining the NRC staff's role in the adjudicatory licensing process. Commenters are invited to examine the following documents which fall within the scope of and are particularly pertinent to the topic addressed in this advance notice of proposed rulemaking.

1. NUREG–0292, "Nuclear Power Plant Licensing: Opportunities for Improvement," June 1977.

2. Marcus A. Rowden, Report: *Achieving a More Effective Licensing Process—Basic Reform Withing Existing Law.* Atomic Industrial Forum, 6–8 November, 1981.

3. NRC Office of General Counsel, *Study of NRC Staff's Role in Contested Nuclear Power Reactor Initial Licensing Proceedings,* June 3, 1982.

4. Draft Report of the Regulatory Reform Task Force, November, 1982.

5. Final Report of the Ad Hoc Committee for Review of Nuclear Reactor Licensing Reform Proposals on The Administrative Reform Proposals of the Regulatory Reform Task Force, July 12, 1983.

These documents have been placed in the Commission's Public Document Room at 1717 H Street, NW., Washington, D. C. 20555 where they are available for inspection and copying for a fee.

List of Subjects in 10 CFR Part 2

Administrative practice and procedure, Antitrust, Byproduct material, Classified information, Environmental protection, Nuclear materials, Nuclear power plants and reactors, Penalty, Sex discrimination, Source material, Special nuclear material, Waste treatment and disposal.

The authority citation for this document is: Sec. 161, Pub. L. 83–703, 68 Stat. 948, as amended (42 U.S.C. 2201).

Dated at Washington, D.C., this 27th day of October, 1983.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

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48 FR 54243

Published 12/1/83

The comment period has been extended and now expires 1/3/84. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

10 CFR Part 2

Role of NRC Staff in Adjudicatory Licensing Hearings; Extension of Comment Period on Advance Notice of Proposed Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Extending comment period.

SUMMARY: In response to requests from the public, the Commission has decided to extend for an additional thirty (30) days the comment period in its advance notice of proposed rulemaking concerning the role of the NRC staff in adjudicatory licensing hearings. The advance notice of proposed rulemaking was published in the Federal Register on November 2, 1983 (48 FR 50550) and provided for the comment period to expire on December 2, 1983. Some members of the public informed the Commission that the period was not long enough to provide substantive and meaningful comments and, accordingly, the Commission has decided to extend it an additional thirty (30) days to January 3, 1984.

DATES: The comment period has been extended and now expires January 3, 1984. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

ADDRESSES: Send written comments or suggestions to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch. Copies of comments received by the Commission may be examined at the NRC Public Document Room, 1717 H Street, NW., Washington, D.C. 20555.

FOR FURTHER INFORMATION CONTACT: Linda S. Gilbert, Office of the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Telephone: (301) 492–7678.

Dated at Washington, D.C., this 28th day of November 1983.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

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48 FR 54499

Published 12/5/83

Comment period expires 1/5/84. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

≫ Comment period extended to 2/20/84.

10 CFR Parts 2 and 72

Hybrid Hearing Procedures for Expansions of Onsite Spent Fuel Storage Capacity at Civilian Nuclear Power Reactors

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission is seeking comments on two versions of a proposed rule that would amend Part 2 of its regulations to implement the hybrid hearing process in Section 134 of the Nuclear Waste Policy

Act of 1982 (NWPA). Pub. L. 97–425, January 7, 1983, 96 Stat. 2201, 42 U.S.C. 10101. Section 134 of the Nuclear Waste Policy Act sets forth a hybrid hearing process to be used in certain contested proceedings on an application for a license or a license amendment to expand the spent nuclear fuel storage capacity at the site of a civilian nuclear power reactor. The hybrid hearing process wouild change existing agency practice by employing less formal procedures in the initial stages of the hearing process and by designating only genuine and substantial issues for resolution in an adjudicatory hearing. Option 1 would require the use of hybrid hearing procedures in all proceedings to which Section 134 applies. Option 2 would permit the use of such procedures at the request of any party to the proceeding. Either version of the proposed rule, if adopted, will affect licenses of commercial nuclear power reactors seeking to expand onsite spent fuel storage capacity through the use of high-density fuel storage racks, fuel rod compaction, the transshipment of spent nuclear fuel to another civilian nuclear power reactor within the same utility system, the construction of additional spent nuclear fuel pool capacity or dry storage capacity, or by other means. The proposed rule, if adopted, will also affect members of the public who seek to participate in such licensing proceedings. A minor conforming change to 10 CFR Part 72 is also proposed.

DATES: Comment period expires January 5, 1984. Comments received after January 5, 1984, will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments filed on or before that date.

ADDRESSES: Submit written comments and suggestions to: Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch. Copies of comments received and the regulatory analysis may be examined at the Commission's Public Document Room, 1717 H Street NW, Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Linda S. Gilbert, U.S. Nuclear Regulatory Commission, Washington, D.C., 20555. Telephone (301) 492–7678.

SUPPLEMENTARY INFORMATION: Section 134 of the NWPA establishes a "hybrid" hearing process to be used in certain contested proceedings on an application for a license or a license amendment to expand the spent nuclear fuel storage capacity at the site of a civilian nuclear power reactor. The hybrid procedures apply to applications filed after January 7, 1983, the date the NWPA was enacted. Section 134 provides, in pertinent part:

> Sec. 134. (a) Oral Argument. In any Commission hearing under section 189 of the Atomic Energy Act of 1954 (42 U.S.C. 2239) on an application for a license, or for an amendment to an existing license, filed after the date of the enactment of this Act, to expand the spent nuclear fuel storage capacity at the site of a civilian nuclear power reactor, through the use of high-density fuel storage racks, fuel rod compaction, the transshipment of spent nuclear fuel to another civilian nuclear power reactor within the same utility system, the construction of additional spent nuclear fuel pool capacity or dry storage capacity, or by other means, the Commission shall, at the request of any party, provide an opportunity for oral argument with respect to any matter which the Commission determines to be in controversy among the parties. The oral argument shall be preceded by such discovery procedures as the rules of the Commission shall provide. The Commission shall require each party, including the Commission staff, to submit in written form, at the time of the oral argument, a summary of the facts, data, and arguments upon which such party proposes to rely that are known at such time to such party. Only facts and data in the form of sworn testimony or written submission may be relied upon by the parties during oral argument. Of the materials that may be submitted by the parties during oral argument, the Commission shall only consider those facts and data that are submitted in the form of sworn testimony or written submission.
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> (b) Adjudicatory Hearing. (1) At the conclusion of any oral argument under subsection (a), the Commission shall designate any disputed question of fact, together with any remaining questions of law, for resolution in an adjudicatory hearing only if it determines that—
>
> (A) There is a genuine and substantial dispute of fact which can only be resolved with sufficient accuracy by the introduction of evidence in an adjudicatory hearing; and
>
> (B) The decision of the Commission is likely to depend in whole or in part on the resolution of such dispute.
>
> (2) In making a determination under this subsection, the Commission—
>
> (A) Shall designate in writing the specific facts that are in genuine and substantial dispute, the reason why the decision of the agency is likely to depend on the resolution of such facts, and the reason why an adjudicatory hearing is likely to resolve the dispute; and
>
> (B) Shall not consider—
>
> (i) Any issue relating to the design, construction, or operation of any civilian nuclear power reactor already licensed to operate at such site, or any civilian nuclear power reactor for which a construction permit has been granted at such site, unless the Commission determines that any such issue substantially affects the design, construction, or operation of the facility or activity for which such license application, authorization, or amendment is being considered; or
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> (ii) Any siting or design issue fully considered and decided by the Commission in connection with the issuance of a construction permit or operating license for a civilian nuclear power reactor at such site, unless (I) such issue results from any revision of siting or design criteria by the Commission following such decision; and (II) the Commission determines that such issue substantially affects the design, construction, or operation of the facility, or activity for which such license application, authorization, or amendment is being considered.
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> (3) The provisions of paragraph (2)(B) shall apply only with respect to licenses, authorizations, or amendments to licenses or authorizations applied for under the Atomic Energy Act of 1954 (42 U.S.C. 2011 et seq.) before December 31, 2005.
>
> (4) The provisions of this section shall not apply to the first application for a license or license amendment received by the Commission to expand onsite spent fuel storage capacity by the use of a new technology not previously approved for use at any nuclear power plant by the Commission.

To implement the hybrid hearing process in Section 134, the Commission is considering two versions of a proposed rule that would amend Part 2 of its regulations. Either version would provide for the use of less formal procedures in the early stage of the hearing process and would designate only genuine and substantial issues for resolution in an adjudicatory hearing. Option I would require the use of hybrid hearing procedures in all proceedings to which Section 134 applies. Option 2 would permit the use of such procedures at the request of any party to the proceeding. These options are discussed in more detail below. The Commission is seeking comments on both proposals to aid in its choice of procedures for the final rule.

Option 1

In Option 1, the Commission proposes to add Subpart K to 10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings." The procedures specified in proposed Subpart K are limited to the types of applications specified in the statute; *i.e.*, applications filed after January 7, 1983, for licenses and license amendments to permit the expansion of spent nuclear fuel storage capacity at the site of a civilian nuclear power reactor. Included within the scope of Subpart K are applications filed pursuant to 10 CFR Part 72 for licensing of an independent spent fuel storage installation (ISFSI) located at the site of a civilian nuclear power reactor. In accordance with paragraph (b)(4) of Section 134, the provisions of proposed Subpart K will not apply to the first application for a license or license amendment to expand onsite spent fuel storage capacity at a particular facility by the use of a new technology not previously approved by the Commission for use at any other nuclear power plant.

The hybrid hearing process in proposed Subpart K consists of an informal first stage which culminates in a legislative-type oral argument designed to identify issues appropriate for resolution in an adjudicatory hearing. Any party may request an oral argument, but issues will not be designated for formal adjudication unless they are found to be genuine and substantial. Thus, the first stage of the hybrid process is essentially a condition precedent to an adjudicatory hearing.

Proposed Subpart K closely tracks the NWPA and substantially departs from existing practice in some respects. As under existing procedure, upon receipt of an application within the scope of the subpart, the Commission will publish a notice of proposed action (or other notice, as appropriate) in the Federal Register.[1] Any person whose interest may be affected may file a request for hearing or petition for leave to intervene that, among other things, identifies the specific aspect or aspects of the subject matter of the proceeding on which intervention is sought.

Proposed § 2.1103(a). This also accords with existing practice. At this point in the proceeding, the proposed hybrid hearing process differs markedly from existing practice. If the petitioner adequately identifies a specific aspect of the proceeding on which intervention is sought and otherwise satisfies the interest and standing requirements in proposed § 2.1103 (a) and (c) (which are identical to those in § 2.714 of the existing rules), the petitioner will be admitted as party to the proceeding. This differs from existing practice in which a petitioner is not admitted as a party to the proceeding unless the petitioner has specified at least one valid "contention." The key procedural provisions implementing the hybrid hearing process are contained in proposed § 2.1104. Because the first stage of the hybrid hearing process established in the NWPA is intended to be informal, a petitioner need not identify "contentions" within the meaning of § 2.714 of the existing Rules of Practice at an early stage in the proceeding. Rather, it will be sufficient if, within 10 days after the presiding officer admits the petitioner as a party, the intervening party files a comprehensive list of issues it wishes to litigate that are alleged to be within the scope of the proceeding. Requests for oral argument must also be filed at this time to be considered timely.[2] After holding such prehearing conferences as may be necessary, the presiding officer will designate in writing which issues are within the scope of the proceeding and will establish a schedule for discovery and subsequent oral argument with respect to those issues.

Factual issues raised in the informal stage of the proceeding will not be subject to formal adjudication unless, after discovery and oral argument, they are shown to be genuine and substantial. Prior to oral argument, Licensing Boards will accept issues for purposes of discovery so long as they are clearly within the scope of the proceeding and are reasonably likely to alert the other parties to the subject matter of the intervening party's concerns. Issues need not be supported with a statement of basis as now required for contentions filed under § 2.714. After the presiding officer determines which proffered issues are within the scope of the proceeding, the presiding officer will establish an appropriate schedule for discovery. Proposed § 2.1104(d). Discovery will proceed in accordance with existing discovery rules in §§ 2.720(h), 2.740, 2.740a, 2.740b, 2.741, 2.742 and 2.744, except that discovery will begin and end on a schedule established by the presiding officer.[3] The Commission recognizes that, initially, discovery will be somewhat broader than under existing practice because the issues will be less focused in the early stages of the proceeding; i.e., there will be no contentions admitted to the proceeding as under current practice. However, discovery will be limited to those factual issues determined by the presiding officer to be within the scope of the proceeding. As discovery proceeds, the Commission expects the issues to become more focused and specific as each party evaluates the responses of the others and narrows its inquiries to areas arguably involving matters of disputed fact.

After discovery is completed, an oral argument will be held. The oral argument will be limited to those matters in controversy that the presiding officer determines are within the scope of the proceeding pursuant to § 2.1104(d). Fourteen (14) days before the date set for oral argument, each party, including the NRC staff, shall submit to the presiding officer a written summary of the facts, data, and arguments upon which the party proposes to rely that are known to the party at that time. Each party shall serve its written submission on every party to the proceeding. Because the purpose of the oral argument is to identify those genuine and substantial disputed issues of fact which must be resolved in an adjudicatory hearing, each party's submission should focus on the specific matters alleged to constitute genuine and substantial disputes of fact and the arguments for or against, as appropriate. During oral argument, the parties may rely only on facts and data contained in written submissions and the presiding officer may consider only those facts and data that are submitted in such form. It must be emphasized that the oral argument is not an evidentiary hearing, but rather a forum for separating genuine factual issues (for subsequent adjudication) from issues of policy or law and/or frivolous factual issues. Accordingly, while parties may call technical experts to support their views, parties are not authorized to cross-examine opposing witnesses. However, the presiding officer may afford the parties an opportunity to suggest in writing questions which they would like the presiding officer to put to opposing witnesses.

Following oral argument, and after due consideration of the various arguments and written submissions, the presiding officer shall make the appropriate findings with respect to each alleged dispute of fact. Proposed § 2.1106. The criteria that the presiding officer must apply in determining which issues, if any, should be resolved in an adjudicatory hearing are identical to the statutory language. The standard is quite strict and is intended to ensure that the resources of all parties to any adjudicatory hearing are focused exclusively on real issues. Appeals from the presiding officer's designation of issues for resolution in an adjudicatory hearing are interlocutory and must await the end of the proceeding, except insofar as they are authorized by existing § 2.714a. Except to the extent qualified in this subpart, any adjudicatory hearing will follow the existing adjudicatory procedures set forth in Subpart G of 10 CFR Part 2. However, because discovery will precede the oral argument, there should ordinarily be no need for further discovery prior to the adjudicatory hearing. Accordingly, the Commission expects that the adjudicatory phase of the hearing will begin expeditiously after the presiding officer designates the issues meeting the criteria in §2.1106.

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[1] Certain spent fuel expansion proceedings, *i.e.*, those that involve applications for an amendment to a facility operating license under 10 CFR Part 50, will be subject to applicable provisions of the Commission's interim final rule implementing Pub. L. 97-415 (the so-called "Sholly amendments"). See 48 FR 14864, 14869 (April 6, 1983). As the Commission recently explained in connection with that rule, reracking of spent fuel pools may or may not involve significant hazards considerations. The staff recently submitted a generic report on that issue. The Commission indicated that it intends to revisit that aspect of the rule and, in the interim, will make a finding on a case-by-case basis. A notice of proposed action or other notice, as appropriate, will be published in accordance with 10 CFR 2.105 or 2.106. If the Commission determines that a particular reracking involves a significant hazards consideration, it will provide an opportunity for a prior hearing; otherwise a hearing may be held after issuance of the amendment. See 10 CFR 50.58, 50.91 and 50.92. In either case, the notice will provide that if a hearing is held, it will be conducted in accordance with the hybrid procedures set forth in this proposed subpart.

[2] Because, under Option 1, the first stage of the hybrid process is in essence a condition precedent to an adjudicatory hearing in those proceedings to which Section 134 applies, the Commission assumes that at least one party will request oral argument. Should no party request oral argument, however, the presiding officer will issue an order terminating the proceeding and the staff will process the application in accordance with existing procedures applicable to uncontested proceedings.

[3] Under existing § 2.740(b)(1), beginning and ending dates for discovery in construction permit and operating license hearings are based on prehearing conference dates. Because proposed § 2.1104(d) gives the presiding officer discretion in calling prehearing conferences, such dates are not necessarily appropriate here.

Option 2

In Option 2, the Commission proposes to implement Section 134 of the NWPA by adding § 2.749a to 10 CFR Part 2. In essence, this option provides for a form of summary disposition procedure to be employed at the request of any party to the proceeding. Proposed § 2.749a differs from the existing summary disposition procedure in that all parties must submit their oral and written positions simultaneously. All other aspects of the hearing process would continue to be governed by the Commission's rules of practice in 10 CFR Part 2, Subpart G. Under Option 2, (as under existing practice), petitioners for intervention must specify at least one admissible contention in order to be admitted as a party. Use of the hybrid procedures is optional rather than mandatory, and the procedures are available in all proceedings to which Section 134 applies. Any party may request, in writing, a decision by the presiding officer that all or any part of the matters involved in the proceeding need not be heard in an adjudicatory proceeding. Proposed § 2.749a(a). Any such request shall be deemed granted upon receipt and the presiding officer shall notify the parties of the date, time, and location of oral argument. Prior to oral argument, discovery will be conducted according to existing rules. Fourteen days before oral argument, each party shall submit a written summary of the facts, data, and arguments on which the party proposes to rely at oral argument. Proposed § 2.749a(b). Following oral argument, the presiding officer shall, by written order, (1) decide all issues of law or fact not designated for adjudication, setting forth all findings, conclusions, and reasons; and (2) designate any remaining questions of fact or law for resolution in an adjudicatory hearing. Proposed § 2.749a(c).

The standards governing the presiding officer's designation of issues for resolution in an adjudicatory hearing appear in paragraphs (d) and (e) of proposed § 2.749a. They follow the statutory language quite closely and are essentially the same as those porposed in Option 1. If the presiding officer determines that no issue is to be designated for an adjudicatory hearing, the order required by proposed § 2.749a(c) shall be in the form of, and shall constitute, an initial decision pursuant to existing §2.760.

Paperwork Reduction Act Statement

This proposed rule contains no new or amended information collection requirements subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.).

Regulatory Flexibility Certification

The proposed rule will not have a significant economic impact upon a substantial number of small entities. Nuclear power plant licensees do not fall within the definition of small businesses found in sectin 3 of the Small Business Act, 15 U.S.C. 632, or the Small Business Size Standards set out in regulations issued by the Small Business Administration at 13 CFR Part 121. The impact on intervenors or potential intervenors will be neutral. The proposed rules, if adopted, will reduce the burden on intervenors during the informal stage of the hybrid hearing by eliminating the need to plead contentions. However, the oral argument may increase case preparation costs by requiring intervenors to demonstrate the existence of a genuine disputed issue in order to trigger an NRC adjudicatory proceeding. Once the adjudicatory hearing commences, an intervenor's costs should decrease because the issues will be more clearly focused than under existing practice. Thus, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 605(b), the NRC hereby certifices that this rule, if promulgated, will not have a significant economic impact upon a substantial number of small entities.

Regulatory Analysis

The Commission has prepared a Regulatory Analysis of the proposed rule assessing the costs and benefits and resource impacts. It may be examined at the Commission's Public Document Room, 1717 H. Street NW., Washington, D.C.

List of Subjects

10 CFR Part 2

Administrative practice and procedure, Antitrust, Byproduct material, Classified information, Environmental protection, Nuclear materials, Nuclear power plants and reactors, Penalty, Sex discrimination, Source material, Special nuclear material, Waste treatment and disposal.

10 CFR Part 72

Manpower training programs, Nuclear materials, Occupational safety and health, Reporting and recordkeeping requirements, Security measures, Spent fuel.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, the Nuclear Waste Policy Act of 1982 and Sections 552 and 553 of Title 5 of the United States Code, the NRC is proposing to adopt the following amendments to 10 CFR Parts 2 and 72.

PART 2—RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS

1. The authority citation for Part 2 is revised to read as follows:

Authority: Secs. 161, 181, 68 Stat. 948, 953, as amended (42 U.S.C. 2201, 2231,); sec. 191, as amended, Pub. L. 87-615, 76 Stat. 409 (42 U.S.C. 2241); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); 5 U.S.C. 552.

Sec. 2.101 also issued under secs. 53,, 62, 63, 81, 103, 104, 105, 68 Stat. 930, 932, 933, 935, 936, 937, 938, as amended (42 U.S.C. 2073, 2092, 2093, 2111, 2133, 2134, 2135); sec. 102, Pub. L. 91–190, 83 Stat. 853, as amended (42 U.S.C. 4332); sec. 301, 88 Stat. 1248 (42 U.S.C. 5871). Secs. 2.102, 2.103, 2.104, 2.105, 2.721 also issued under secs. 102, 103, 104, 105, 183, 189, 68 Stat. 936, 937, 938, 954, 955 as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2233, 2239). Section 2.105 also issued under Pub. L. 97–415, 96 Stat. 2073 (42 U.S.C. 2239). Secs. 2.200–2.206 also issued under secs. 186, 234, 68 Stat. 955, 83 Stat. 444, as amended (42 U.S.C. 2236, 2282); sec. 206, 88 Stat. 1246 (42 U.S.C. 5846). Secs. 2.600–2.606 also issued under sec. 102, Pub. L. 91–190, 83 Stat. 853, as amended (42 U.S.C. 4332). Sections 2.700a, 2.719 also issued under 5 U.S.C. 554. Secs. 2.754, 2.760, 2.770 also issued under 5 U.S.C. 557. Sections 2.790 also issued under sec. 103, 68 Stat. 936, as amended (42 U.S.C. 2133) and 5 U.S.C. 552. Secs. 2.800 and 2.808 also issued under 5 U.S.C. 553. Sec. 2.809 also issued under 5 U.S.C. 553 and sec. 29, Pub. L. 85–256, 71 Stat. 579, as amended. (42 U.S.C. 2039). [Subpart K or § 2.749a] also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97–425, 96 Stat. 2230 (42 U.S.C. 10154). Appendix A also issued under sec. 6, Pub. L. 91–580, 84 Stat. 1437 (42 U.S.C. 2135).

2. *For Option 1 only:* Part 2 is amended by adding a new Subpart K to 10 CFR Part 2 to read as follows:

Subpart K—Hybrid Hearing Procedures for Expansions of Onsite Spent Fuel Storage Capacity at Civilian Nuclear Power Reactors

Sec.
2.1100 Purpose.
2.1101 Scope of subpart.
2.1102 Notice of proposed action.
2.1103 Requests for hearing or petitions to intervene.
2.1104 Filing of list of issues; requests for oral argument.
2.1105 Discovery; oral argument.
2.1106 Designation of issues for hearing.
2.1107 Applicability of other sections.

§ 2.1100 Purpose.

The purpose of this subpart is to implement section 134 of the Nuclear Waste Policy Act of 1982 (Pub. L. 97–425, 96 Stat. 2230, 42 U.S.C. 10154), which

establishes hybrid hearing procedures to be used in certain contested proceedings on applications for a license or license amendment to expand the spent fuel storage capacity at the site of a civilian nuclear power plant. The hybrid hearing procedures consist of an oral argument, preceded by discovery, with respect to any matter in controversy among the parties which the Commission determines to be within the scope of the proceeding, followed by an adjudicatory hearing on any genuine and substantial disputed question of fact.

§ 2.1101 Scope of subpart.

This subpart prescribes procedures applicable to contested proceedings on applications for a license or license amendment, filed after January 7, 1983, to expand the spent fuel storage capacity at the site of a civilian nuclear power plant, through the use of high density fuel storage racks, fuel rod compaction, the transshipment of spent nuclear fuel to another civilian nuclear power reactor within the same utility system, the construction of additional spent nuclear fuel pool capacity or dry storage capacity, or by other means. This subpart also applies to proceedings on applications for a license under 10 CFR Part 72 to store spent fuel in an independent spent fuel storage installation located at the site of a civilian nuclear power reactor. This subpart shall not apply to the first application for a license or license amendment to expand the spent fuel storage capacity at a particular site through the use of a new techology not previously approved by the Commission for use at any other nuclear power plant.

§ 2.1102 Notice of proposed action.

(a) In connection with each application filed after January 7, 1983, for a license or an amendment to a license to expand the spent fuel storage capacity at the site of a civilian nuclear power plant, for which the Commission has not found that a hearing is required in the public interest and for which an adjudicatory hearing has not yet been convened, the Commission will, prior to acting thereon, cause to be published in the **Federal Register** a notice of proposed action. In the case of an application for an amendment to an operating license for a nuclear power reactor, the provisions of §§ 50.58, 50.91 and 50.92 of this chapter will govern the type of notice required and the timing of the hearing relative to the issuance of the amendment; however, any hearing held on the application shall be conducted in accordance with the procedures in this subpart.

(b) The notice of proposed action will set forth:

(1) The nature of the action proposed; and

(2) The manner in which a copy of the safety analysis, appropriate environmental documents and the ACRS report, if any, may be obtained or examined.

(c) The notice of proposed action will provide that, within thirty (30) days from the date of publication of the notice in the **Federal Register**, or such lesser period authorized by law as the Commission may specify:

(1) The applicant may file a request for a hearing; and

(2) Any person whose interest may be affected by the proceeding may file a petition for leave to intervene or a request for a hearing.

(d) The notice of proposed action will specify that any hearing held on the application shall be conducted in accordance with the procedures set forth in this subpart.

(e)(1) If no request for a hearing or petition for leave to intervene is filed within the time prescribed in the notice, the Director of Nuclear Reactor Regulation or the Director of Nuclear Material Safety and Safeguards, as appropriate, may take the proposed action, inform the appropriate State and local officials, and publish in the **Federal Register** a notice of issuance of the license or other action.

(2) If a request for a hearing or a petition for leave to intervene is filed within the time prescribed in the notice, the presiding officer, who shall be an Atomic Safety and Licensing Board established by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel, will rule on the request or petition and will issue an appropriate order.

§ 2.1103 Requests for hearing or petitions to intervene.

(a)(1) Any person whose interest may be affected by the proceeding and who desires to participate as a party shall file a written petition for leave to intervene or a request for a hearing. The petition or request shall be filed not later than the time specified in the notice of proposed action or as provided by the Commission, the presiding officer, or the atomic safety and licensing board designed to rule on the petition or request. Nontimely filings will not be entertained absent a determination by the Commission, the presiding officer, or the atomic safety and licensing board designated to rule on the petition or request, that the petition or request should be granted based upon a balancing of the following factors in addition to those set out in paragraph (c) of this section:

(i) Good cause, if any, for failure to file on time.

(ii) The availability of other means whereby the petitioner's interest will be protected.

(iii) The extent to which the petitioner's participation may reasonably be expected to assist in developing a sound record.

(iv) The extent to which the petitioner's interest will be represented by existing parties.

(v) The extent to which the petitioner's participation will broaden the issues or delay the proceeding.

(2) The petition shall set forth with particularity the interest of the petitioner in the proceeding, how that interest may be affected by the results of the proceeding, including the reasons why the petitioner should be permitted to intervene, with particular reference to the factors in paragraph (c) of this section, and the specific aspect or aspects of the subject matter of the proceeding as to which petitioner wishes to intervene.

(b) Any party to a proceeding may file an answer to a petition for leave to intervene within ten (10) days after service of the petition, with particular reference to the factors set forth in paragraph (c) of this section. However, the staff may file such an answer within fifteen (15) days after service of the petition.

(c) The Commission or the presiding officer shall promptly rule in writing on each request for a hearing or petition to intervene. No request for a hearing or petition to intervene may be granted unless the Commission or the presiding officer determines that the requestor or petitioner meets judicial standards for standing. For purposes of this subpart, a petitioner whose petition for leave to intervene is granted shall be considered a party to the proceeding. In ruling on a petition for leave to intervene the following factors, among other things, shall be considered:

(1) The nature of the petitioner's right under the Act to be made a party to the proceeding.

(2) The nature and extent of the petitioner's property, financial, or other interest in the proceeding.

(3) The possible effect of any order which may be entered in the proceeding on the petitioner's interest.

(d) An order permitting intervention or granting a hearing may be conditioned on such terms as the Commission, or the presiding officer may direct in the interests of (1) restricting irrelevant, duplicative, or repetitive evidence and argument; (2) having common interests represented by a spokesperson; and (3) retaining authority to determine priorities and control the scope of the hearing.

(e) In any case in which, after consideration of the factors set forth in paragraph (c) of this section, the Commission or the presiding officer finds that the petitioner's interest is limited to one or more specific aspects of the subject matter of the proceeding, an order allowing intervention shall limit his or her participation accordingly.

(f) A person permitted to intervene becomes a party to the proceeding subject to any limitations imposed pursuant to paragraph (g) of this section.

(g) Unless otherwise expressly provided in the order allowing intervention, the granting of a petition for leave to intervene does not change or enlarge the scope of the proceeding as specified in the notice of proposed action.

§ 2.1104 Filing of list of issues; requests for oral argument.

(a) Within ten (10) days after an order granting a petition for leave to intervene, an intervening party shall file a comprehensive list of the issues which it seeks to have determined in the proceeding, and a statement as to why each issue set forth is within the scope of the proceeding. Additional time for filing the list may be granted upon a showing of good cause. Additional issues may be entertained after the filing of the list required by this subsection only upon a favorable balancing of the factors in § 2.1103(a)(1).

(b) Any party to the proceeding may file a response to the list of issues within ten (10) days after service of the list. However, the staff may file its reponse within (15) days after service of the list.

(c)(1) Within ten (10) days after an order granting a petition for leave to intervene, any party may request an oral argument. Requests for oral argument shall be in writing and shall be filed with the presiding officer. A timely request for oral argument shall be deemed granted.

(2) Untimely requests for oral argument may be granted by the presiding officer upon a showing of good cause by the requesting party for failure to file on time and after providing the other parties an opportunity to respond to the untimely request.

(d) After holding such prehearing conferences as may be necessary, the presiding officer shall issue a written order designating which issues filed pursuant to paragraph (a) of this section are within the scope of the proceeding, and establishing a schedule for discovery and subsequent oral argument with respect to those issues.

(e) If no party to the proceeding requests oral argument, or if all untimely requests for oral argument are denied, the presiding officer shall issue a written order terminating the proceeding and the application shall be processed by the staff in accordance with procedures applicable to uncontested proceedings.

§ 2.1105 Discovery; oral argument.

(a) Oral argument shall be limited to those matters in controversy among the parties which the presiding officer determines to be within the scope of the proceeding pursuant to § 2.1104. The argument shall be preceded by discovery to the extent permitted by §§ 2.720(h), 2.740, 2.740a, 2.740b, 2.741, 2.742 and 2.744. Nothwithstanding the provisions of § 2.740(b)(1), discovery shall begin and end at such times as the presiding officer shall order. A party other than the staff or license or license amendment applicant may obtain discovery and participate in oral argument with respect to only those issues raised by that party which are determined to be within the scope of the proceeding by the presiding officer.

(b) Each party, including the staff, shall submit to the presiding officer fourteen (14) days prior to the date set for oral argument a written summary of the facts, data, and arguments which are known to the party at such time and upon which such party proposes to rely at the time of the oral argument either to support or to refute the existence of a genuine and substantial dispute of fact. Each party's written submission shall be simultaneously served on all other parties to the proceeding. Only facts and data in the form of sworn testimony or written submission may be relied upon by the parties during oral argument, and the presiding officer shall consider only those facts and data submitted in such form.

(c) The presiding officer shall have broad discretion in conducting the oral argument to ensure that an adequate record is made to support the findings required in § 2.1106, including the discretion to request from opposing parties questions in the nature of the cross-examination which such parties would like the presiding officer to address to any opposing witness presented at the oral argument. This provision shall not be construed as authorizing any party to the proceeding to conduct cross-examination of opposing witnesses at the oral argument.

§ 2.1106 Designation of issues for hearing.

(a) After due consideration of the written filings and the facts and data presented at the oral argument, the presiding officer shall promptly designate in a written order any disputed questions of fact, together with any remaining questions of law, for resolution in an adjudicatory hearing. The written order shall include a statement of findings and conclusions, together with the reasons or basis for them, with respect to any issue of law or fact heard at the oral argument that is not designated for resolution at the adjudicatory hearing. The presiding officer may not designate *sua sponte* any issues for resolution in the adjudicatory hearing.

(b) No question of law or fact shall be designated for resolution in an adjudicatory hearing unless the presiding officer determines that—

(1) There is a genuine and substantial dispute of fact which can only be resolved with sufficient accuracy by the introduction of evidence in an adjudicatory hearing; and

(2) The decision of the Commission is likely to depend in whole or in part on the resolution of such dispute.

(c) In making a determination under this subsection, the presiding officer—

(1) Shall designate in writing the specific facts that are in genuine and substantial dispute, the reason why the decision of the agency is likely to depend on the resolution of such facts, and the reason why an adjudicatory hearing is likely to resolve the dispute; and

(2) Shall not consider—

(i) Any issue relating to the design, construction, or operation of any civilian nuclear power reactor already licensed to operate at such site, or any civilian nuclear power reactor for which a construction permit has been granted at such site, unless the presiding officer determines that any such issue substantially affects the design, construction, or operation of the facility or activity for which such license application, authorization, or amendment is being considered; or

(ii) Any siting or design issue fully considered and decided by the Commission in connection with the issuance of a construction permit or operating license for a civilian nuclear power reactor at such site, unless (A) such issue results from any revision of siting or design criteria by the Commission following such decision; and (B) the presiding officer determines that such issue substantially affects the design, construction, or operation of the facility or activity for which such license application, authorization, or amendment is being considered.

(d) The provisions of paragraph (c)(2) of this section shall apply only with respect to licenses, authorizations, or amendments to licenses or authorizations applied for before December 3, 2005.

((e) Appeals from the presiding officer's designation of issues are interlocutory and must await the end of the proceeding, except to the extent authorized by § 2.714a of this chapter.

§ 2.1107 Applicability of other sections.

The provisions of Subparts A and G relating to construction permits, operating licenses, and amendments thereto apply, respectively, to construction permits, operating licenses, and amendments thereto that are subject to this subpart, except as qualified by the provisions of this subpart.

PART 72—LICENSING REQUIREMENTS FOR THE STORAGE OF SPENT FUEL IN AN INDEPENDENT SPENT FUEL STORAGE INSTALLATION (ISFSI)

3. *For Option 1 only:* The authority citation for Part 72 is revised to read as follows:

Authority: Secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 68 Stat. 929, 930, 932, 933, 934, 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2232, 2233, 2234, 2236, 2237, 2282); sec. 274, Pub. L. 86–373, 73 Stat. 688, as amended (42 U.S.C. 2021); sec. 201, 202, 206, 88 Stat. 1242, 1243, 1246, and amended (42 U.S.C. 5841, 5842, 5846); Pub. L. 95–601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851); sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332); sec. 134, Pub. L. 97–425, 96 Stat. 2230.

4. *For Option 1 only:* In § 72.34, paragraph (a) is revised to read as follows:

§ 72.34 Public hearings.

(a) In connection with each application for a license of an amendment to a license under this part, the Commission shall issue or cause to be issued a notice of hearing in accordance with § 2.104 of this chapter, or a notice of proposed action in accordance with § 2.105 or § 2.1102 of this chapter, as appropriate. Except as provided in paragraph (b) of this section, a hearing may not be held until after 30 days' notice and publication once in the **Federal Register.**

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PART 2—RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS

5. *For Option 2 only:* Section 2.749a is added to read as follows:

§ 2.749a Authority of presiding officer to dispose of certain issues on the pleadings.

(a) Any party may request, in writing, a decision by the presiding officer that all or any part of the matters involved in a spent fuel proceeding need not be heard in an adjudicatory hearing. Spent fuel proceedings, pursuant to Part 50 of this chapter, include an application for a license, or for an amendment to an existing license, filed after January 7, 1983 and prior to December 31, 2005, to expand the spent nuclear fuel storage capacity at the site of a civilian nuclear power reactor, through the use of high-density fuel storage racks, fuel rod compaction, the transshipment of spent nuclear fuel to another civilian nuclear power reactor within the same utility system, the construction of additional spent nuclear fuel pool capacity or dry storage capacity, or by other means.

(b) A request pursuant to paragraph (a) of this section shall be deemed granted upon receipt and the presiding officer shall notify all the parties as to the date, time and location of oral argument. Such oral argument will not be scheduled until all parties have completed discovery, pursuant to 10 CFR 2.740–2.742 and 2.744, on the matters raised in the request. Fourteen (14) days prior to the date set for oral argument, each party, including the NRC Staff, shall submit, to the presiding officer, and shall simultaneously serve on all other parties, a detailed written summary of all of the facts, data, and arguments which are known to the party at such time and upon which the party proposes to rely at the oral argument. Only facts and data in the form of sworn testimony or other written submission may be relied upon by the parties during oral argument and the presiding officer shall only consider those facts and data submitted in such form.

(c) After due consideration of the oral presentation and the written facts and data presented at the oral argument, the presiding officer shall promptly by written order:

(1) Decide all issues of law or fact not designated for resolution in an adjudicatory hearing, setting forth fully the presiding officer's findings and conclusions, with the reasons or bases for them; and

(2) Designate any remaining questions of fact or law for resolution in an adjudicatory hearing.

(d) No question of law or fact shall be designated for resolution in an adjudicatory hearing unless the presiding officer determines that:

(1) There is a genuine and substantial dispute of fact which can only be resolved with sufficient accuracy by the introduction of evidence in an adjudicatory hearing; and

(2) The decision of the Commission is likely to depend in whole or in part on the resolution of such dispute.

(e) In making a determination under paragraph (d) of this section, the presiding officer shall designate in writing the specific facts that are in genuine and substantial dispute, the reasons why the decision of the Commission is likely to depend on the resolution of such facts, and the reasons why an adjudicatory hearing is likely to resolve the dispute. The presiding officer shall not consider:

(1) Any issue relating to the design, construction, or operation of any civilian nuclear power reactor already licensed to operate at such site, or any civilian nuclear power reactor for which a construction permit has been granted at such site, unless the presiding officer determines that any such issue substantially affects the design, construction, or operation of the facility or activity for which such license application, authorization, or amendment is being considered; or

(2) Any siting or design issue fully considered and decided by the Commission in connection with the issuance of a construction permit or operating license for a civilian nuclear power reactor at such site, unless (i) such issue results from any revision of siting or design criteria by the Commission following such decision; and (ii) the presiding officer determines that such issue substantially affects the design, construction, or operation of the facility or activity for which such license application, authorization, or amendment is being considered.

(f) If the presiding officer determines that no issue is to be designated for an adjudicatory hearing, the order required by paragraph (c) of this section shall be in the form of, and shall constitute the initial decision of the presiding officer in accordance with the provisions of § 2.760 of these rules.

(g) This section shall not apply to a proceeding on the first application for a license or license amendment to expand on-site fuel storage capacity by the use of a new technology not previously approved for use at any nuclear power plant by the Commission.

Dated at Washington, D.C. this 29th day of November, 1983.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

≫ 49 FR 414

Published 1/4/84

The comment period has been extended and now expires 2/20/84. Comments received after this date will be considered if it is practicable to do so, but assurance of consideration cannot be given except as to comments received on or before that date.

10 CFR Parts 2 and 72

Hybrid Hearing Procedures for Expansion of Onsite Spent Fuel Storage Capacity at Civilian Nuclear Power Reactors

AGENCY: Nuclear Regulatory Commission.

ACTION: Extension of comment period.

SUMMARY: On December 5, 1983 (48 FR 54499), the NRC published for public comment two versions of a proposed rule to implement the hybrid hearing process established by Section 134 of the Nuclear Waste Policy Act of 1982.

The notice provided that the comment period would expire on January 5, 1984. The Utility Nuclear Waste Management Group (UNWMG) has requested a sixty-day extension of the comment period. In view of the importance of the proposed rule, the amount of time that the UNWMG suggests is required in order to provide meaningful comments on behalf of its forty-three member utilities, and the desirability of developing a final rule as soon as practicable, the NRC has decided to extend the comment period for an additional forty-five (45) days to February 20, 1984.

DATES: The comment period has been extended and now expires February 20, 1984. Comments received after that date will be considered if it is practicable to do so, but assurance of consideration cannot be given except as to comments received on or before that date.

ADDRESSES: Send written comments or suggestions to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch. Copies of comments received may be examined at the NRC Public Document Room, 1717 H. Street NW., Washington, D.C. 20555.

FOR FURTHER INFORMATION CONTACT: Linda S. Gilbert, Office of the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Telephone: (301) 492-7678.

Dated at Washington, D.C. this 28th day of December 1983.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,
Secretary to the Commission.

49 FR 14698
Published 4/12/84
Comment period expires 6/11/84
Comments received after 6/11/84 will be considered if it is practical to do so, but assurances of consideration cannot be given except as to comments recieved on or before this date.

10 CFR Parts 2 and 50

Request for Public Comment on Regulatory Reform Proposal Concerning the Rules of Practice, Rules for Licensing of Production and Utilization Facilities

AGENCY: Nuclear Regulatory Commission.

ACTION: Request for public comment on suggestions for procedural changes in nuclear power plant licensing process.

SUMMARY: In November, 1981, the NRC created a Regulatory Reform Task Force charged with conducting a detailed evaluation of the NRC licensing process for nuclear power plants. The Commission directed the Task Force to develop proposals both for legislation and for rule changes to improve the process by which nuclear power plants are licensed.

The Task Force reviewed a large number of proposals for reforming the licensing process through rule changes. A number of such proposals were forwarded to the Commission in a Draft Report in November, 1982.[1] The fact that a proposal was included in the Draft Report indicates only that a consensus of Task Force members believed that further evaluation of the proposal was appropriate. Members of the Task Force frequently held strongly differing views on the merits of individual proposals. Hence, presentation of the proposal does not signify that the particular proposal necessarily commanded the support of a majority of Task Force members.

The Draft Report was reviewed internally by a Senior Advisory Group, composed of NRC personnel, and by an Ad Hoc Committee for the Review of Nuclear Reactor Licensing Reform Proposals. The latter group, established

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[1] The Draft Report contained proposed rule changes concerning backfitting, the hearing process, separation of functions/*ex parte*, and participation of the NRC staff in initial license proceedings. It also included legislative proposals.

by the Commission, was composed of non-NRC persons with experience in the Commission's licensing process and procedures. In both the Senior Advisory Group and the Ad Hoc Committee, different members held quite different views on the merits of particular proposals, and so advised the Commission.

On November 17, 1983, the Commission discussed the package of proposals at a public meeting. The Commission decided, based on all the information before it, to solicit public comment on the entire package of proposals before deciding on a particular course of action with respect to any or all of the individual proposals.

The individual proposals thus are not Commission proposals, nor do they necessarily command the support of a majority of the Task Force, the Senior Advisory Group, or the Ad Hoc Committee. Rather, they are suggestions for improvements in the licensing process which have been brought to the Commission's attention and on which the Commission now seeks the views of the public.

As a drafting matter, the proposals have been cast in the form of "proposed rules." It should be emphasized, however, that the present document is *not* a notice of proposed rulemaking. If the Commission decides, based upon the comments received, that a particular proposal warrants adoption through rulemaking, then a formal notice of proposed rulemaking will be required.

DATES: Comment period expires June 11, 1984. Comments received after June 11, 1984 will be considered if it is practical to do so, but assurances of consideration cannot be given except as to comments filed on or before the due date specified herein.

ADDRESS: Submit written comments and suggestions to: the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch. Examine copies of comments received at: the Commission's Public Document Room at 1717 H Street NW., Washington, D.C.

FOR FURTHER INFORMATION CONTACT: James R. Tourtellotte, Regulatory Reform Task Force, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Telephone: (202) 492-7678.

SUPPLEMENTARY INFORMATION:

Introduction

In November, 1981, the NRC created a Regulatory Reform Task Force charged to conduct a detailed evaluation of the NRC licensing process for nuclear power plants. The Commission directed that the Task Force develop proposals for legilation and for regulatory changes to improve the licensing process for nuclear power plants. The Task Force conducted its review and submitted a report identifying certain deficiencies in the existing licensing process and containing proposals for amendments to the NRC's regulations to remedy these deficiencies. This notice of proposed rulemaking contains amendments to the NRC's regulations designed to implement the Task Force's recommendations.

The Regulatory Reform Task Force found that the quality of the existing hearing process can and should be improved. The three principal parts of the hearing process, i.e., the screening process, the actual conduct of the hearing, and the decisionmaking process, were closely examined and changes in all three areas were proposed. In the discussion which follows, the improvements proposed within eath of the three categories are summarized. A section-by-section analysis of the proposed changes follows. The section-by-section analysis explains the major proposed changes in more detail. However, minor conforming changes of an editorial or insignificant nature are not broken out for specific discussion.

Many of the proposed changes are applicable only to "initial licensing proceedings" (as defined in proposed § 2.4(r)) and, therefore, do not affect proceedings under Subpart B of 10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings" to modify, suspend or revoke a license. For example, the proposed creation of the screening Atomic Safety and Licensing Board to rule on hearning requests, petitions for leave to intervene and contentions is applicable only to initial licensing. However, certain proposed changes will, if adopted, affect all agency proceedings, including enforcement proceedings. Examples in this category include the proposed requirement that judicial standards for determining whether a potential party has standing will be applied to determine whether a hearing request or intervention petition should be granted and the proposed elimination of the Atomic Safety and Licensing Appeal Board as an intermediate appellate tribunal.

No amendments to Subparts D and E of Part 2 are proposed at this time. Those subparts specify the additional procedures applicable to standardized plant designs subject to the requirements of Appendices M and N of 10 CFR Part 50. Standardization is the subject of a separate rulemaking. Any necessary changes to Subparts D and E will be addressed in that rulemaking.

I. Summary of Improvements

A. Screening Process

For purposes of the discussion which follows, the "screening process" refers to the process for determining whether a hearing should be held and, if so, what issues should be heard by the presiding officer. The Regulatory Reform Task Force identified three major ways in which the screening process could be improved. The first major improvement is the proposed creation of a screening Atomic Safety and Licensing Board ("screening board"). In initial licensing proceedings all requests for hearings, petitions for leave to intervene, and proposed contentions will be referred to a screening board. Under existing practice, the presiding officer designated to conduct the hearing usually rules on all such requests. The screening board will determine whether standing requirements have been met, whether a hearing or petition for intervention should be granted and which contentions are admissible. Late filed contentions and issues which the presiding officer conducting the hearing proposes to consider *sua sponte* will also be referred to a screening board for a determination of admissibility. As a central "clearinghouse" for hearing requests, intervention petitions, and contentions, the screening board will add a necessary measure of predictability to such rulings. Under present practice, this predictability is lacking because intervention rulings are made by numerous Atomic Safety and Licensing Boards. Public comment is particularly invited on the advisability of creating a screening board or whether the existing system permitting the presiding officer designated to conduct the hearing to rule on intervention matters and raise issues *sua sponte* should be retained.

Second, under existing Commission practice, a person who fails to meet judicial standards of standing may nonetheless be permitted to intervene (or to trigger a hearing) in Commission proceedings. See *Portland General Electric Co.* (Pebble Springs Nuclear Plant, Units 1 and 2), CLI–76–27, NRC 610 (1976). The proposed rule requires presiding officers to apply judicial requirements for standing in determining whether a person may trigger a hearing or intervene in an ongoing proceeding. Requiring a person to demonstrate standing will help ensure that all participants in NRC proceedings have an interest in the proceeding sufficient to justify their participation in the proceeding and the necessary commitment of additional Commission resources.

The third proposed improvement would raise the threshold for the admission of contentions to essentially require the proponent of the contention to tender evidence suggesting the existence of a genuine factual dispute. This is consistent with Supreme Court precedent. See *Costel v. Pacific Legal Foundation*, 445 U.S. 198, 214 (1980), citing *Weinberger v. Hynson, Westcott and Running, Inc.*, 412 U.S. 609 at 620–621 (1973). Under existing regulations, once a petitioner is admitted to the proceeding he or she is only required to draft contentions which set forth the basis for the contentions with reasonable specificity. 10 CFR 2.714(a)(3). No inquiry is made into the merits of the contention and the petitioner is under no obligation to demonstrate the existence of some factual support for the contention as a precondition for its acceptance. In practice, this requirement may be met by copying contentions from another proceeding involving another reactor. Thus, an intervenor need not fully understand a contention and frivolous contentions are easily admitted. The increased evidentiary threshold for admission of contentions will ensure that frivolous contentions are not litigated in NRC proceedings.

B. Conduct of the Hearing

A number of improvements are proposed to improve the conduct of the hearing itself. First, under the proposed rules, pretrial discovery will be more rigorously controlled by presiding officers. To prevent abusive or burdensome discovery, a party will be required to sign each discovery request, answer, objection, or motion. The signature certifies, among other things, that the party's discovery filing is based on good faith and not primarily for the purpose of delay. Permissible discovery against the staff will also be appropriately limited to matters which form the basis for the staff's position on a given issue; discovery requests may not require the staff to perform additional work on matters beyond what is needed to support the staff's position on the issue or to explain why matters not relied on by the staff were not considered.

Second, substantial changes are proposed in how evidence is presented in initial licensing proceedings. To the fullest extent possible, all evidence, direct and rebuttal, will be submitted in writing; a special need for live testimony, including cross-examination, must be demonstrated. In this regard, cross-examination plans which assure that cross-examination would be meaningful must be submitted to assist the presiding officer in deciding whether to permit cross-examination. Legal scholars and critics of the current system have suggested that the scientific and technical issues, well stated and properly understood, may generally be amenable to resolution on written pleadings, that credibility of the witnesses usually is not a central issue and that testimony of a scientific nature is well-suited to being reduced to writing. Under existing practice most *direct* testimony in licensing proceedings is submitted in writing. See 10 CFR 2.743(b). Limitations on cross-examination are also desirable because, although the existing rules authorize the Licensing Boards to Control cross-examination, the Boards often fail to do so. In addition, in practice, the value of cross-examination is often diminished by unskilled questioning. This results in a cluttered trial record.

Third, a new provision is proposed which would allow the screening board or the presiding officer conducting the hearing to appoint a panel of technical subject matter experts. The screening board could request the assistance of the experts to help it determine whether there is a technical basis for reaching a conclusion that a proposed contention raises a genuine issue of disputed fact. The presiding officer conducting the hearing could appoint a panel to sit with him or her to hear the evidence on a particular issue. The panel would then prepare a report with recommendations or conclusions. Panel members could be appointed from inside or from outside the agency, but each member would be subject to the existing notice and disqualification procedures contained in § 2.704.

A number of miscellaneous improvements are also suggested. The *sua sponte* rule, which allows presiding officers to raise issues on their own motion, would be tightened so that in all but the most unusual situations the scope of the hearing woud be confined to the disputed issues of fact properly placed into controversy by the parties; to encourage the use of summary procedures to dispose of issues prior to hearing, summary disposition motions could be filed at any stage of the proceeding; motions which are not controverted by other parties must be granted; and an express provision is added to recognize that the Commission may designate a qualified hearing examiner to preside in initial licensing proceedings in lieu of a three member licensing board.

C. Improvements to the Decisionmaking Process

Several improvements to the decisionmaking process are also proposed. The most fundamental is the proposed removal of the Atomic Safety and Licensing Appeal Board as an independent, intermediate administrative appellate tribunal. The Appeal Board will function as a staff office of the Commission with the responsibility to draft proposed decisions for Commission review. It will no longer function as an administrative "court of appeals." This change will permit the Commission itself to expeditiously resolve the important policy questions which frequently arise in the course of its licensing and enforcement proceedings. In addition, the Commission will also be able to exercise a greater degree of supervision over the conduct of its proceedings. Finally, removal of the Appeal Board as a separate appellate tribunal should also expedite final agency action on adjudicated matters by eliminating a layer of review.

Another major improvement is the proposed addition of a rule which will allow the expeditious codification of generic factual issues resolved in initial licensing proceedings as regulations. This rule is intended to preclude the relitigation of generic factual issues resolved in one proceeding in subsequent proceedings involving similar facilities or reactors. The rule would only apply to generic factual issues which are litigated to a conclusion, i.e. issues not dismissed on summary disposition or withdrawn by a party, to ensure that the merits of the issues have been fully considered in the proceeding. Once resolved, the generic issue will be expeditiously issued as a proposed rule on the basis of the hearing record with a 45-day period for public comment. If the Commission adopts the rule after considering the public comments, the generic issue could not be litigated in subsequent adjudications unless special circumstances could be shown pursuant to § 2.758.

The third proposed improvement would prohibit an intervening party from filing proposed findings of fact and conclusions of law, or filing exceptions to initial decisions, on issues not placed in controversy by that party. Present practice permits any party to file proposed findings, conclusions of law, and exceptions on any issue in the proceeding, including issues not raised by it. The purpose of this change is to ensure that presiding officers and the agency appellate tribunal, i.e. the Commission, are able to focus on the disputed issues in the proceeding as presented and argued by the parties with the chief interest in the issue. The proponent of a contention is expected to present and argue its case on the contention much more persuasively than a party who elects to argue an issue only in legal papers filed after the evidentiary portion of hearing is completed. These filing limitations are expected to improve the decisionmaking process by allowing presiding officers and the Commission to focus their energies on the arguments made by the proponents (and opponents) of each particular issue.

Fourth, the immediate effectiveness rule will be restored for all initial decisions. Following the TMI accident, the rule was substantially modified to require a limited Appeal Board or

Commission review of initial decisions authorizing construction permits or operation at more than 5 percent of full power. Experience gained since the TMI accident has shown this restriction on effectiveness has not had a positive effect on safety and has been procedurally cumbersome. Restoration of the immediate effectiveness rule does not affect the right of a party to seek a stay of an initial decision pursuant to the provisions of § 2.788.

Finally, under existing practice, the Director of Nuclear Reactor Regulation or Nuclear Material Safety and Safeguards, as appropriate, issues licenses authorized by initial decisions. Under the proposed rules, responsibility for license issuance will rest with the Executive Director for Operations, the chief staff officer of the Commission.

II. Section-by-Section Analysis

1. Definitions (10 CFR 2.4)

Two new definitional sections are proposed. Proposed § 2.4(r) defines "initial licensing" in accordance with the guidance contained in the 1947 Attorney General's Manual on the Administrative Procedure Act. See pp. 50–51 of the Manual. In general, all agency proceedings for the issuance or amendment of licenses fall within the definition, but proceedings in the nature of enforcement or renewal actions are not included. The definition of "initial licensing" is added so that procedures applicable to "initial licensing" are clearly distinguished from procedures which may be applicable to other types of proceedings. Proposed § 2.4(s) defines the term "presiding officer." This term is used in numerous provisions in Part 2, but has heretofore not been explicitly defined. Note that the screening atomic safety and licensing board (see proposed § 2.721) is a "presiding officer."

2. Notice of Hearing (10 CFR 2.104)

The primary purpose of revised § 2.104 is to limit presiding officers to deciding disputed issues of fact. Section 2.104 has also been reorganized to clearly distinguish between different types of applications. Paragraph (a) is limited to mandatory construction permit proceedings. The major difference between this provision and the existing provisions applicable to construction permit proceedings is that in contested proceedings, except for issues which must be considered under NEPA, presiding officers will consider only disputed issues placed in controversy by the parties. Therefore, the notice of hearing will no longer state that in contested proceedings the presiding officer will automatically consider the issues listed in existing § 2.104(b)(1). Paragraph (b) of revised § 2.104 is applicable to all other notices of hearing for proceedings within the scope of subpart A of Part 2, except for antitrust proceedings held in connection with a CP or OL license. (The notice for antitrust proceedings is contained in revised § 2.104(c)). Proposed § 2.104(b) differs from the existing provision (§ 2.104(c)) primarily in that, as in the case of CP proceedings, except for NEPA issues which must be considered by the presiding officer, only controverted issues will be considered by the presiding officer. As noted above, proposed § 2.104(c), specifies the notice of hearing for antitrust proceedings and is substantially the same as the existing provision (§ 2.104(d)). Proposed paragraph (d) is identical with existing paragraph (e).

3. Notice of Opportunity for Hearing (10 CFR 2.105)

Proposed § 2.105, "Notice of Opportunity for Hearing," differs in several minor respects from the existing provision. First, proposed § 2.105(e)(2) reflects the creation of the screening atomic safety and licensing board (see proposed § 2.721) by specifying that the screening board will rule on requests for hearing. Second, a new paragraph (d)(3) is proposed which provides that the notice of opportunity for hearing will state that a person's participation in any hearing held on the proposed action will be limited to the issues specified in the notice of hearing, unless good cause is shown for considering additional issues. This provision is intended to ensure that persons whose interest may be affected by the proceeding raise issues on a timely basis by responding to the notice of opportunity for hearing rather than waiting until a notice of hearing, if any, is subsequently published. Third, paragraph (e)(1) is changed to designate the Executive Director for Operations as the individual who may take the proposed action if a timely request for hearing is not filed. The existing provision designates the Director of Nuclear Reactor Regulation or Director of Nuclear Material Safety and Safeguards. The purpose of this change is to enhance the concept of a strong Executive Director for Operations and ensure management accountability for licensing. Finally, the notice published pursuant to this section will now be called a "notice of opportunity for hearing" rather than a "notice of proposed action."

4. Exceptions (10 CFR 2.700a)

A new paragraph (c) is added to § 2.700a, "Exceptions," which provides that the Commission, notwithstanding any other provision to the contrary in Part 2, may prescribe such alternative procedures as it deems necessary in initial licensing proceedings. The notice of hearing of opportunity for hearing will specify the procedures. This provision is intended to allow the Commission to make full use of the procedural flexibility allowed under the Administrative Procedure Act. See *Vermont Yankee Nuclear Power Corporation* v. *NRDC*, 435 U.S. 519 (1978).

5. Designating of Presiding Officer, Disqualification, Unavailability (10 CFR 2.704)

Minor revisions to § 2.704 are proposed to specify that an administrative law judge may be designated by the Commission to preside at hearings. A conforming change in paragraph (d) is also proposed to allow the Chief Administrative Law Judge to designate a replacement for an administrative law judge who may become unavailable during the course of a proceeding.

6. Requests for Hearings and Petitions to Intervene (10 CFR 2.714)

Section 2.714 has been reorganized and substantially modified. The major changes from the existing intervention rule are as follows:

- A potential intervenor must meet judicial standards for standing in order to be admitted to an NRC proceeding. Proposed § 2.714(f). The purpose of this provision is to abolish the concept of discretionary intervention which the Commission first recognized in *Portland General Electric Co.* (Pebble Springs Nuclear Plant, Units 1 and 2) CLI–76–27, 4 NRC 610 (1976).
- Contentions must be filed at the time the request for hearing or petition for leave to intervene is filed. Proposed § 2.714(g)(2). The existing provision requires only that an "aspect" of the subject matter of the proceeding be identified at the time the hearing request or intervention petition is filed and final contentions need not be filed until 15 days prior to the special prehearing or prehearing conference. The purpose of requiring the filing of contentions with the request for hearing or petition to intervene is to require the identification of issues as early as possible in the proceeding. The applicant's safety and environmental reports are publicly available by this time in the Commission's Public Document and Local Public Document Rooms. However, since the staff's environmental reviews are not completed until after the time for filing requests or petitions has passed, amended or additional contentions based on the staff environmental documents may be filed if the data or conclusions differ significantly from those in the applicant's documents. Proposed § 2.714(g)(1)(ii). Non-timely filings of contentions will not be entertained absent a determination by the screening ASLB or other presiding officer designated to rule on contentions that the filing should be permitted based

on a balancing of the factors listed in paragraph (c)(4). The factors to be considered in ruling on late filed contentions are identical to those specified in the current rule. Therefore, the screening ASLB or other presiding officer will have a considerable body of NRC case law to assist it in making any such determinations.

- The threshold for admission of contentions is raised. Proposed contentions must show that a genuine dispute exists with the applicant on an issue of law, fact or policy and the showing must include references to the *specific* portions of the application which are disputed. The contention must be supported by a concise statement of the alleged facts or expert opinion, together with specific sources and documents of which the petitioner is aware, which will be relied on to establish the facts or expert opinion. The purpose of the increased threshold is to ensure that the resources of all parties are focused on real rather than imaginary issues.
- A provision has been added (proposed § 2.714(i)(4)) which provides that a contention raising only an issue of law will not be admitted for resolution in an evidentiary hearing but shall be decided on the basis of briefs and/or oral argument.
- In initial licensing proceedings, the screening board will rule on requests for hearings, petitions for intervention and contentions contained therein. (Proposed § 2.714(j)). In other types of proceedings, e.g. enforcement proceedings, these rulings will be made by the presiding officer designated by the Commission.

7. Appeals From Certain Rulings on Petitions for Leave To Intervene and/or Requests for Hearing (10 CFR 2.714a)

Section 2.714a is proposed to be modified so that appeals of such rulings lie with the Commission rather than the Atomic Safety and Licensing Appeal Board. This change is consistent with the removal of the Appeal Board as an intermediate appellate tribunal.

8. Consolidation of Parties of Construction Permit or Operating License Proceedings (10 CFR 2.715a)

Proposed § 2.715a is expanded in scope. Absent a showing by a party that its rights would be prejudiced, the proposed rule would require presiding officers to consolidate parties in initial licensing proceedings after first offering the parties an opportunity to consolidate voluntarily. State and local government entities appearing in NRC proceedings represent unique interests. Therefore, the Commission would not expect presiding officers to consolidate these participants with private intervenors.

9. Subpoenas (10 CFR 2.720)

Discovery against the NRC staff is tightened in proposed § 27.20(h)(2)(ii). Specifically, while interrogatories may seek to elicit factual information reasonably related to the staff's position at the hearing, interrogatories may not be used to require that staff to explain why alternative data, assumptions or analyses were not relied on in the staff review. In addition, interrogatories may not require the staff to perform additional research or analytical work beyond that needed to support the staff's position on any particular matter. These provisions are intended to avoid the unnecessary expenditure of scarce staff resources at pretrial stages of the hearing on matters not directly pertinent to the staff's position in the hearing. Of course, it would still be permissible for a party to argue at the hearing that the staff should have performed additional studies or relied on alternative data. Finally, a specific reference is added regarding the Commission's Public and Local Public Document Rooms. The purpose of this provision is to make clear that if an interrogatory requests information already in the Public Document Rooms, such information is "resonably obtainable from any other source" and, therefore, need not be provided. A sufficient answer to such a question would be the title and page reference to the relevant document.

10. Atomic Safety and Licensing Boards (10 CFR 2.721)

Section 2.721 is revised to authorize the establishment of one or more screening atomic safety and licensing boards. A screening board will be composed of three members with the same qualifications as members of a regular atomic safety and licensing board. The principal function of the screening board will be to rule on requests for hearings, petitions for leave to intervene and contentions in all initial licensing proceedings. The screening board may hold prehearing conferences, appoint expert panels and utilize any other procedures available to presiding officers to enable it to rule on hearing requests, intervention petitions and contentions. The screening board will then transfer the proceeding with the list of admitted issues to the presiding officer designated to conduct the hearing. If no party has demonstrated standing and filed an admissible contention, the screening board will dismiss the proceeding except in construction permit applications in which there is a mandatory hearing requirement. Late filed contentions and revised or new contentions filed after the staff's environmental documents are issued will be referred back to the screening board for a determination of admissibility, even if filed after the hearing has commenced. Similarly, issues which the presiding officer proposes to raise *sua sponte* during the course of a proceeding will be referred to the screening board for a determination of admissibility.

The screening board will serve as a centralized and specialized forum for resolution of the difficult questions faced by presiding officers in resolving issues of standing and the admissibility of contentions. It is expected that the screening board(s) will develop substantial expertise in resolving these issues and add a measure of predictability and consistency to intervention rulings. This has been difficult to achieve under present practice because a multiplicity of licensing boards now make these rulings.

A new paragraph (e) is also proposed to explicitly recognize that the Commission may appoint a qualified administrative law judge in lieu of an atomic safety and licensing board to preside in its proceedings.

11. Special Assistants to the Presiding Officer and Expert Panels (10 CFR 2.722)

Section 2.722 is revised to permit the presiding officer, including a screening board, to appoint an expert panel consisting of one, three or five members with specific subject matter expertise. The panel will assist the presiding officer designated to conduct the hearing by hearing evidentiary presentations, either oral or written, within its subject matter expertise and may examine the witnesses of the parties as a technical interrogator. The panel will advise the presiding officer of its recommendations and conclusions through an on-the-record report. The report is advisory only. In the case of an expert panel appointed by a screening board, the panel will assist the board in determining whether sufficient evidence had been tendered to conclude that there exists a genuine issue of disputed fact.

It is expected that expert panels will be used only in those situations when the subject matter of the issue at hand is both highly technical and not within the general expertise of the technical members of the licensing board conducting the hearing. The proposed rule provides for one, three or five expert panel members to avoid an evenly divided panel report. Panel members may be selected from either inside or outside the agency.

All are subject, however, to the notice and disqualification provisions described in § 2.704.

12. Motions (10 CFR 2.730)

A new paragraph is added to § 2.730 to expressly provide that uncontroverted motions shall be granted by the presiding officer to the extent authorized by law. In addition, the term "presiding officer" is substituted for the narrow reference to "the Board" in paragraph (e).

13. Examination of Experts (10 CFR 2.733)

A minor addition to § 2.733 is proposed to make clear that examination and cross-examination of expert witnesses by technically qualified individuals may be permitted only to the extent that oral direct or cross-examination is otherwise permitted. See the discussion of revised § 2.743.

14. General Provisions Governing Discovery (10 CFR 2.740)

Section 2.740 has been revised to ensure that presiding officers have ample tools to prevent and remedy unnecessary, burdensome or abusive discovery. Proposed paragraph (b)(2) allows the presiding officers upon his or her own initiative, or upon a motion for a protective order, to limit the use of discovery, including the number of interrogatories a party may serve. In addition, proposed paragraph (g) requires that every discovery request, response, objection thereto, or motion for a protective order be signed by the party or its authorized representative. The signature constitutes a certification that, among other things, the signatory has read the filing and that it has been filed in good faith and not primarily to cause delay. Failure to sign negates the effect of the document. The presiding officer may impose sanctions if a certification is falsely made.

15. Evidence (10 CFR 2.743)

Section 2.743 is substantially revised. The major proposed changes, applicable only to initial licensing proceedings, are as follows:

- Direct and rebuttal testimony will be submitted in written form unless otherwise ordered by the presiding officer for good cause. A schedule for the filing of such testimony is established in proposed paragraph (b)(3).
- Cross-examination is permitted only upon the request of a party filed within 10 days after service of the written testimony concerning a particular issue. Cross-examination is available to an intervening party only on those issues on which the requesting party has proffered an admissible contention. This is a departure from the present practice in which oral cross-examination is the rule rather than the exception and which does not necessarily limit cross-examination by an intervening party to issues proffered by it. The NRC staff, a governmental representative admitted to the proceeding pursuant to § 2.715(c), and the license applicant may move to cross-examine on any admitted contention in the proceeding. The proposed rule places the burden of establishing the need for cross-examination on the requesting party, including the NRC staff, a governmental representative and the license applicant. A motion to cross-examine, among other things, must include a detailed cross-examination plan and a statement as to why written testimony could not establish the same points. See proposed paragraphs (b)(5)–(8). The cross-examination plan will be kept confidential by the presiding officer until the completion of the cross-examination, if allowed, at which time it will be inserted into the record. This provision is intended to ensure an adequate record is made for possible appellate review of orders granting or denying cross-examination.

16. Authority of Presiding Officer To Dispose of Certain Issues on the Pleadings (10 CFR 2.749)

Section 2.749 is modified in two respects. First, the rule as proposed would permit summary disposition motions to be filed at any time during the proceeding rather than, as provided in the existing rule "within such time as may be fixed by the presiding officer." This change is intended to give the parties maximum flexibility to file such motions and to make it possible to terminate litigation at any point during the proceeding when it becomes apparent that a genuine issue of fact is no longer in dispute. Second, the proposed rule eliminates the present prohibition against determining on summary disposition the ultimate issue as to whether a construction permit should issue. This prohibition is unnecessary.

17. Proposed Findings and Conclusions (10 CFR 2.754)

Paragraph (c) of § 2.754 is revised to limit filings of proposed findings of fact and conclusions of law by parties who do not have the burden of proof or who have only a limited interest in the proceeding to those issues placed in contention by the party. The proponent of a contention is responsible for making its case on the issue at the hearing. The revision recognizes that the proponent of a contention is in the best position to present the arguments in support of the contention and is intended to ensure that presiding officers are not inundated with a multiplicity of extraneous filings from persons with no stake in the resolution of a particular issue. Since license applicants have the burden of proof and the NRC staff has a general interest in the proceeding to ensure that the public health and safety and environmental values are protected, the limitation on filings in paragraph (c) are not applicable to either; each has an obvious interest in filing proposed findings and conclusions on most, if not all, contested issues. Presiding officers will be expected to strike those portions of proposed findings and conclusions of law filed in contravention of this section.

18. Authority of Presiding Officer To Regulate Procedures in a Hearing (10 CFR 2.754)

Section 2.754 is revised to make mandatory the Commission's presently permissive admonition that presiding officers should limit the number of witnesses whose testimony may be cumulative, strike argumentative, repetitious, cumulative, or irrelevant evidence. This is intended to tighten up the proceeding and produce a better record.

19. Codification of Generic Factual Issues Resolved in Initial Licensing Proceedings (10 CFR 2.758a)

A new § 2.758a is proposed. This section requires that generic factual issues resolved in initial licensing proceedings be considered for promulgation as final Commission rules after public comment is sought in accordance with the rulemaking provisions of the Administrative Procedure Act. The purpose of this provision is to ensure that generic issues resolved in an evidentiary proceeding are not relitigated in subsequent proceedings. Generic factual issues codified as final rules will be subject to challenge in Commission licensing proceedings only to the extent permitted under the existing provisions of § 2.758, "Consideration of Commission rules and regulations in adjudicatory proceedings," i.e. upon a showing of special circumstances.

20. Initial Decisions in Contested Proceedings on Applications for Facility Operating Licenses (10 CFR 2.760a)

Section 2.760a is revised to revoke the 1979 relaxation of the *sua sponte* rule for review of uncontested matters by adjudicatory boards. See 44 FR 67088 (November 23, 1979). Experience under the relaxed standard has indicated that issues have been raised *sua sponte* which do not warrant such consideration. For example, contentions raised and later dropped by intervenors have been adopted by some Licensing Boards with little apparent regard for the seriousness of the issues involved. Accordingly, the *sua sponte* authority of presiding officers to raise new issues will be limited to extraordinary circumstances and is to be used sparingly. A similar change is proposed to be made to § 2.785(b)(2). Any issue(s) proposed to be raised *sua sponte* by the presiding officer conducting the hearing is to be referred with an explanation to the screening Atomic Safety and Licensing Board for a determination whether the matter should be considered at the hearing.

21. Appeals to the Commission From Initial Decisions (10 CFR 2.762)

Section 2.762 is revised to provide that an intervening party may file exceptions only on those issues which the party placed in controversy or sought to place in controversy in the proceeding. This will reverse the rule established in *Northern States Power Co.* (Prairie Island Nuclear Generating Plant, Units 1 and 2), ALAB–244, 8 AEC 857, 863 (1974), that an intervenor can appeal on all issues, whether or not raised by his or her own contentions. The rationale for this revision is the same as that discussed in regard to proposed § 2.754(c), *supra.*

22. Immediate Effectiveness of Decisions Directing Issuance or Amendment of Construction Permit or Operating License (10 CFR 2.764)

Section 2.764 is revised to return to the pre-TMI rule that initial decisions of presiding officers are immediately effective. Accordingly, it is proposed that paragraphs (e) and (f), which provide for Appeal Board and/or Commission consideration of effectiveness of initial decisions authorizing construction permits and operating licenses at greater than 5% power, be deleted. The Commission has tentatively concluded that the lessons learned from TMI have been sufficiently factored into the licensing and regulatory process to make limited Commission review on the question of effectiveness no longer necessary. Stays of initial decisions may continue to be sought in accordance with the provisions of § 2.788.

23. Elimination of the Atomic Safety and Licensing Appeal Board (10 CFR 2.785, 2.786, and 7.787)

The Commission proposes to delete §§ 2.785, 2.786 and 2.787. These provisions establish and describe the functions of the Atomic Safety and Licensing Appeal Board. Unlike most agencies, the Commission's adjudicative process resembles that of the Federal Court system. The Commission sits as the administrative "supreme court," the Appeal Boards sit as the administrative "courts of appeal" and Licensing Boards and administrative law judges sit as the "district" or trial courts. The amendments would substantially change the existing three-tiered adjudicative structure of the NRC by eliminating the Appeal Board as the middle rung of this process. While the Appeal Board would retain its existing review functions, it will function as a staff office of the Commission. It will not issue decisions, but will prepare draft opinions and rulings for the Commission. After appropriate review, the Commission will issue its decision. Thus, the Appeal Board will function as a Commission staff office responsible for reviewing and drafting decisions on adjudicatory matters, rather than as an intermediate appellate tribunal. Elimination of the intermediate tribunal would have several benefits. First, the Commission will be able to supervise its adjudicatory process more closely. This supervision is especially crucial when, as happens frequently, issues of a policy nature arise during the course of its proceedings. Second, elimination of sequential Appeal Board and possible Commission review should expedite final agency action on adjudicatory matters. Third, some duplication of resource commitment would be eliminated since the need for separate review by the Commission's offices of Policy Evaluation and General Counsel could be eliminated or reduced. Conforming changes to § 2.788 are also proposed to eliminate references to stays of Appeal Board decisions.

24. Appendix A to Part 2

"Statement of General Policy and Procedure: Conduct of Proceedings for the Issuance of Construction Permits and Operating Licenses for Production and Utilization Facilities for Which a Hearing is Required Under Section 189a of the Atomic Energy Act of 1954, as Amended," is proposed to be deleted as unnecessary.

25. License Required (10 CFR 50.10)

Two conforming changes to § 50.10 are proposed to note that the Executive Director for Operations rather than the Director of Nuclear Reactor Regulation will issue limited work authorizations. This is consistent with the revisions discussed *supra,* which provide that the Executive Director rather than particular Office Directors will issue licenses authorized after hearing.

Paperwork Reduction Act Review

The Nuclear Regulatory Commission has submitted this proposed rule to the Office of Management and Budget for such review as may be appropriate under the Paperwork Reduction Act of 1980, Pub. L. 96–511, 94 Stat. 2812, 44 U.S.C. § 3501 *et seq.*

Regulatory Flexibility Statement

The proposed rule will reduce the procedural burden on NRC licensees by improving the hearing process. The impact on intervenors or potential intervenors will be neutral. While intervenors or potential intervenors will have to meet a higher threshold to gain admission to NRC proceedings and, thereby, incur some additional economic costs in preparing its request for hearing or intervention request, the proposed improvements should reduce an intervenors costs once the hearing commences. Thus, in accordance with the Regulatory Flexibility Act, 5 U.S.C. § 605(b), the NRC hereby certifies that this rule, if promulgated, will not have a significant economic impact upon a substantial number of small entities.

List of Subjects

10 CFR Part 2

Administrative practice and procedure, Antitrust, Byproduct material, Classified information, Environmental protection, Nuclear materials, Nuclear power plants and reactors, Penalty, Sex discrimination, Source material, Special nuclear material, Waste treatment and disposal.

10 CFR Part 50

Antitrust, Classified information, Fire prevention, Incorporation by reference, Intergovernmental relations, Nuclear power plants and reactors, Penalties, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and Sections 552 and 553 of Title 5 of the United States Code, notice is hereby given that adoption of the following amendments to 10 CFR Parts 2 and 50 are contemplated:

It is proposed that 10 CFR Parts 2 and 50 be amended as follows:

PART 2—RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS

1. The authority citation for Part 2 continues to read as follows:

Authority: Secs. 161, 68 Stat. 948, 953 (42 U.S.C. 2201, 2231); sec. 191, as amended, Pub. L. 87–615, 76 Stat. 409 (42 U.S.C. 2241); sec. 201, Pub. L. 93–438, 88 Stat. 1242, as amended by Pub. L. 94–79, 89 Stat. 413 (42 U.S.C. 5841); 5 U.S.C. 552.

(Section 2.101 also issued under secs. 53, 62, 81, 103, 104, 105, 68 Stat. 930, 932, 935, 936, 937, 938, as amended (42 U.S.C. 2073, 2093, 211, 2133, 2134, 2135); sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332); sec. 301, 88 Stat. 1248 (42 U.S.C. 5871). Sections 2.102, 2.104, 2.105, 2.721 also issued under secs. 102, 103, 104, 105, 183, 68 Stat. 936, 937, 938, 954 955, as amended (42 US.C. 2132, 2133, 2134, 2135, 2233, 2239). Sections 2.200–2.206 also issued under sec. 186, 68 Stat. 955 (42 U.S.C. 2236); sec. 206, 88 Stat. 1246 (42 U.S.C. 5846). Sections 2.600–2.606, 2.730, 2.772 also issued under sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332). Sections 2.700a, 2.719 also issued under 5 U.S.C. 554. Sections 2.754, 2.760, 2.770 also issued under 5 U.S.C. 557. section 2.790 also issued under sec. 103, 68 Stat. 936, as amended (42 U.S.C. 2133). Sections 2.800–2.807 also issued under 5 U.S.C. 553. section 2. 808 also issued under 5

U.S.C. 553 and sec. 102, 83 Stat. 853 (42 U.S.C. 4332). Section 2.809 also issued under 5 U.S.C. 553 and sec. 29, Pub. L. 95–209, 91 Stat. 1483 (42 U.S.C. 2039).

2. In § 2.4, paragraph (r) is redesignated as paragraph (u), paragraph (s) is redesignated as paragraph (r), and new paragraphs (s) and (t) are added to read as follows:

§ 2.4 Definitions.

* * * * *

(s) "Initial licensing" includes any proceeding on an application for a construction permit, operating license, or any other license for a facility or other activity, or for any amendment or modification thereof, but normally does not include licensing proceedings involving the renewal, revocation, suspension, annulment, withdrawal, or agency-initiated modification or amendment of licenses.

(t) "Presiding officer" means one or more members of the Commission, an administrative law judge, an atomic safety and licensing board, a screeing atomic safety and licensing board, or a named officer who has been delegated authority to preside in an evidentiary hearing under this chapter.

* * * * *

3. Section 2.104 is revised to read as follows:

§ 2.104 Notice of hearing.

(a)(1) In the case of an application for the issuance of a construction permit for a facility of the type described in § 50.21(b) or § 50.22 of this chapter or a testing facility, the Secretary will issue a notice of hearing to published in the Federal Register as required by law at least thirty (30) days, prior to the date set for hearing in the notice.[1] In addition, the notice (other than a notice pursuant to paragraph (c) of this section) shall be issued as soon as practicable after the application has been docketed: Provided, that if the Commission, pursuant to § 2.101(a)(2), decides to determine the acceptability of the application on the basis of its technical adequacy as well as completeness, the notice shall be issued as soon as practicable after the application has been tendered. The notice will state:

(i) The time, place, and nature of the hearing and/or prehearing conference, if any;

(ii) The authority under which the hearing is to be held;

(iii) The matters of fact and law to be considered; and

(iv) The time within which answers to the notice or petitions for leave to intervene shall be filed.

(2) Except in the case of a construction permit proceeding noticed pursuant to paragraph (c) of this section and unless the Commission determines otherwise, the notice of hearing will state in implementation of paragraph (a)(1)(iii) of this section:

(i) That, if the proceeding is not a contested proceeding, the presiding officer will determine (A) without conducting a de novo evaluation of the application, whether the application and the record of the proceeding contain sufficient information, and the review of the application by the Commission's staff has been adequate, to support the safety findings required by the Atomic Energy Act of 1954, as amended, proposed to be made and the issuance of the construction permit proposed by the Executive Director for Operations, and (B) if the application is for a construction permit for a nuclear power reactor, a testing facility, a fuel reprocessing plant, or other facility whose construction or operation has been determined by the Commission to have a significant impact of the environment whether the review conducted by the Commission pursuant to the National Environmental Policy Act (NEPA) has been adequate.

(ii) That regardless of whether the proceeding is contested or uncontested, the presiding officer will, in accordance with Part 51 of this chapter:

(A) Determine whether the requirements of section 102(2)(A), (C) and (E) of the National Environmental Policy Act and Part 51 of this chapter have been complied with in the proceeding;

(B) Independently consider the final balance among conflicting factors contained in the record of the proceeding with a view to determining the appropriate action to be taken; and

(C) Determine whether the construction permit should be issued, denied, or appropriately conditioned to protect environmental values.

(b)(1) In the case of any other application within the scope of this subpart in which the presiding officer has determined that a hearing should be held, the presiding officer will issue a notice of hearing to be published in the Federal Register as required by law at least fifteen (15) days prior to the date set for hearing in the notice. The notice will state:

(i) The time, place, and nature of the hearing and/or prehearing conference, if any;

(ii) The authority under which the hearing is to be held;

(iii) The matters of fact and law to be considered; and

(iv) The time within which answers to the notice or petition for leave to intervene shall be filed.

(2) Except in the case of an operating license proceeding noticed pursuant to paragraph (c) of this section, and unless the Commission determines otherwise, if the application is for an operating license for a nuclear power reactor, a testing facility, or a fuel reprocessing plant, or other facility whose operation has been determined by the Commission to have a significant impact on the environment, the notice of hearing will state in implementation of paragraph (b)(1)(iii) of this section that the presiding officer will determine whether, in accordance with the requirements of Part 51 of this chapter, the operating license should be issued as proposed.

(c) In an application for a construction permit or an operating license for a facility on which a hearing is required by the Act or this chapter, or in which the Commission finds that a hearing is required in the public interest to consider the antitrust aspects of the application, the notice of hearing will, unless the Commission determines otherwise, state:

(1) A time of the hearing, which will be as soon as practicable after the receipt of the Attorney General's advice and compliance with sections 105 and 189a of the Act and this part:[2]

(2) The presiding officer for the hearing who shall be either an administrative law judge or an atomic safety and licensing board established by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel;

(3) That the presiding officer will consider and decide whether the activities under the proposed license would create or maintain a situation inconsistent with the antitrust laws described in section 105a of Act; and

(4) That matters of radiological health and safety and common defense and security, and matters raised under the National Environmental Policy Act of 1969, will be considered at another hearing for which a notice will be published pursuant to paragraphs (a) and (b) of this section, unless otherwise

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[1] If the notice of hearing does not specify the time and place of initial hearing, a subsequent notice will be published in the Federal Register which will provide at least thirty (30) days notice of the time and place of that hearing. After this notice is given the presiding officer may reschedule the commencement of the initial hearing for a later date or reconvene a recessed hearing without again providing thirty (30) days notice.

[2] As permitted by subsection 105c of the Act, with respect to proceedings in which an application for a construction permit was filed prior to December 19, 1970, and proceedings in which a written request for antitrust review of an application for an operating license to be issued under section 104b has been made by a person who intervened or sought by timely written notice to the Commission to intervene in the construction permit proceeding for the facility to obtain a determination of antitrust considerations or to advance a jurisdictional basis for such determination within 25 days after the date of publication in the Federal Register or notice of filing of the application for an operating license or December 19, 1970, whichever is later, the Commission may issue a construction permit or operating license which contains the conditions specified in § 50.55b of this chapter before the antitrust aspects of the application are finally resolved.

authorized by the Commission.

(d) The Secretary will give timely notice of the hearing to all parties and to other persons, if any, entitled by law to notice. The Secretary will transmit a notice of hearing on an application for a facility license or for a license for receipt of waste radioactive material from other persons for the purpose of commercial disposal by the waste disposal licensee or for a license to receive and possess high-level radioactive waste at a geologic repository operations area pursuant to Part 60 of this chapter to the Governor or other appropriate official of the State and to the chief executive of the municipality in which the facility is to be located or the activity is to be conducted or, if the facility is not to be located or the activity conducted within a municipality, to the chief executive of the county (or to the Tribal organization if it is to be so located or conducted within an Indian reservation).

4. In § 2.105, the section heading, the introductory text of paragraph (b), and paragraphs (a), (d), and (e) are revised to read as follows:

§ 2.105 Notice of opportunity for hearing.

(a) If a hearing is not required by the Act or this chapter, and if the Commission has not found that a hearing is in the public interest, it will, prior to acting thereon, cause to be published in the **Federal Register** a notice of opportunity for hearing with respect to an application for—

(1) A license for a facility;

(2) A license for receipt of waste radioactive material from other persons for the purpose of commercial disposal by the waste disposal licensee. All licenses issued under Part 61 of this chapter shall be so noticed.

(3) An amendment of a license specified in paragraph (a)(1) or (2) of this section and which involves a significant hazards consideration;

(4) A license to receive and possess high-level radioactive waste at a geologic repository operations area pursuant to Part 60 of this chapter.

(b) The notice of opportunity for hearing will set forth—

* * * * *

(d) The notice of opportunity for hearing will provide that within thirty (30) days from the date of publication of the notice in the **Federal Register**, or such lesser period authorized as the Commission may specify:

(1) The applicant may file a request for a hearing; and

(2) Any person whose interest may be affected by the proceeding may file a request for a hearing.

(3) Any person's participation as a party in any hearing held on the proposed action shall be limited to the issues specified in the notice of hearing unless the screening Atomic Safety and Licensing Board determines that good cause for considering additional issues is shown in accordance with the provisions of § 2.714.

(e)(1) If no request for a hearing is filed within the time prescribed in the notice, the Executive Director for Operations may take the proposed action, inform the appropriate State and local officials, and publish in the **Federal Register** a notice of issuance of the license or other action.

(2) If a request for a hearing is filed within the time prescribed in the notice, the screening Atomic Safety and Licensing Board will rule on the request in accordance with the provisions of § 2.714.

* * * * *

5. In § 2.106, paragraph (a) is revised to read as follows:

§ 2.106 Notice of issuance.

(a) The Executive Director for Operations will cause to be published in the **Federal Register** notice of, and will inform the State and local officials specified in § 2.104(d) of the issuance of:

(1) A license or an amendment of a license for which a notice of opportunity for hearing has been previously published; and

(2) An amendment of a license for a facility of the type described in § 50.21(b) or § 50.22 of this chapter, or a testing facility, whether or not a notice of opportunity for hearing has been previously published.

* * * * *

6. Section 2.700 is revised to read as follows:

§ 2.700 Scope of Subpart.

The general rules in this subpart govern procedure in all adjudications initiated by the issuance of a order to show cause, an order pursuant to § 2.205(e), a notice of hearing, a notice of opportunity for hearing issued pursuant to § 2.105, or a notice issued pursuant to § 2.102(d)(3).

7. In § 2.700a, paragraph (c) is added to read as follows:

§ 2.700a Exceptions.

* * * * *

(c) Notwithstanding any other provisions to the contrary in this Part, in any initial licensing proceeding the Commission may prescribe such procedures as it deems necessary. The notice of opportunity for hearing or notice of hearing will specify the procedures.

8. In § 2.703, paragraph (a) is revised to read as follows:

§ 2.703 Notice of hearing.

(a) In a proceeding in which the terms of a notice of hearing are not otherwise prescribed by this part, the order or notice of hearing will state:

(1) The nature of the hearing, and its time and place, or a statement that the time and place will be fixed by subsequent order;

(2) The legal authority and jurisdication under which the hearing is to be held;

(3) The matters of fact and law asserted or to be considered; and

(4) The time within which an answer or petition for leave two intervene shall be filed.

* * * * *

9. In § 2.704, paragraphs (a), (d) introductory text and (d)(1)(i) are revised to read as follows:

§ 2.704 Designation of presiding officer, disqualification, unavailability.

(a) The Commission may provide in the notice of hearing that one or more members of the Commission, an administrative law judge, an atomic safety and licensing board, or a named officer who has been delegated final authority in the matter, shall preside. If the Commission does not so provide, the Chairman of the Atomic Safety and Licensing Board Panel will issue an order designating an atomic safety and licensing board appointed pursuant to section 191 of the Atomic Energy Act of 1954, as amended, or, if the Commission has not provided for the hearing to be conducted by an atomic safety and licensing board, the Chief Administrative Law Judge will issue an order designating an administrative law judge appointed pursuant to section 3105 of title 5 of the United States Code.

* * * * *

(d) If a presiding officer or a designated member of an atomic safety and licensing board becomes unavailable during the course of a hearing, the Commission, the Chief Administrative Law Judge, or the Chairman of the Atomic Safety and Licensing Board Panel, as appropriate, will designate another presiding officer or atomic safety and licensing board member. If he becomes unavailable after the hearing has been concluded:

(1)(i) The Commission or the Chief Administrative Law Judge, as appropriate may designate another presiding officer to make the decision; or

* * * * *

10. Section 2.714 is revised to read as follows:

§ 2.714 Requests for hearings and petitions to intervene.

(a) *Requests for hearings.* Any person whose interest may be affected in a proceeding noticed pursuant to §§ 2.102(d)(3), 2.105, 2.202, or 2.204 may file a written request for hearing which includes the information specified in paragraph (d) of this section. The request shall be filed within the time specified in paragraph (c) of this section. The requestor must also file a list of the contentions which the requestor seeks to have litigated in the hearing within the time specified in paragraph (g) of this section.

(b) *Petitions to intervene.* Any person whose interest may be affected by a proceeding in which a notice of hearing has been published and who desires to participate as a party in such a proceeding shall file a written petition for intervention which includes the information specified in paragraph (d) of this section. The petition shall be filed within the time specified in paragraph (c) of this section. The petitioner must also file a list of the contentions which petitioner seeks to have litigated in the hearing within the time specified in paragraph (g) of this section.

(c) *Time for filing requests for hearing and petitions to intervene.* (1) A request for hearing shall be filed not later than the time specified in the notice of opportunity for hearing or notice published pursuant to §§ 2.102(d)(3), 2.202 or 2.204.

(2) A petition for leave to intervene shall be filed not later than the time specified in the notice of hearing.

(3) Non-timely filings will not be entertained absent a determination by the Commission or the presiding officer designated to rule on the intervention petition or request for hearing, that the intervention or hearing should be granted based upon a balancing of the following factors in addition to those set our in paragraph (f) of this section:

(i) Good cause, if any, for failure to file on time.

(ii) The availability of other means whereby the requestor's or petitioner's interest will be protected.

(iii) The extent to which the requestor's or petitioner's participation may reasonably be expected to assist in developing a sound record.

(iv) The extent to which the requestor's or petitioner's interest will be represented by existing parties.

(v) The extent to which the requestor's or petitioner's participation will broaden the issues or delay the proceeding.

(d) *Contents of request for hearing or petition to intervene.* A request for hearing or petition to intervene shall be filed with the Secretary of the Commission and served on such others as may be specified in the notice. It shall be filed in the format required by § 2.708 and shall set forth with particularity:

(1) The nature of the requestor's or petitioner's right under the Act to be made a party to the proceeding.

(2) The nature and extent of the requestor's or petitioner's property, financial or other interest which could be affected by the outcome of the proceeding.

(3) The possible effect of any order which may be entered in the proceeding on the requestor's or petitioner's interest.

(e) *Answer to request for hearing or petition to intervene.* The applicant or licensee and any party to the proceeding may file an answer to a petition for leave to intervene or request for a hearing within ten (10) days after service of the request or petition. The staff may file an answer within fifteen (15) days after service of the request for hearing or the petition.

(f) *Ruling on request for hearing or petition to intervene.* The Commission or the presiding officer designated to rule on the intervention petition or request for hearing shall, in ruling on the request or petition shall consider the following factors, among other things:

(1) The nature of the requestor's or petitioner's right under the Act to be made a party to the proceeding.

(2) The nature and extent of the requestor's or petitioner's property, financial, or other interest in the proceeding.

(3) The possible effect of any order which may be entered in the proceeding on the requestor's or petitioner's interest. No request for hearing or petition to intervene may be granted unless the Commission or the presiding officer designated to rule on the request or petition determines that the requestor or the petitioner meets judicial standards for standing.

(g) *Filing of contentions.* (1) The requestor or the petitioner shall also file a list of the contentions which the requestor or the petitioner seeks to have litigated in the hearing. Each contention shall consist of a specific statement of the issue of law, fact or policy to be raised or controverted. In addition, except for contentions advanced in enforcement proceedings noticed under §§ 2.105, 2.202 or 2.204, the requestor or the petitioner must provide the following information with respect to each contention:

(i) A brief explanation of the bases of the contention.

(ii) A concise statement of the alleged facts or expert opinion which support the contention and which at the time of the filing the requestor or petitioner intends to rely upon in proving its contention at the hearing, together with references to the specific sources and documents of which petitioner is aware which will be relied on to establish such facts or expert opinion.

(iii) Sufficient information (which may include information pursuant to § 2.714(g)(1) (i) and (ii) to show that a genuine dispute exists with the applicant on an issue of law, fact or policy. This showing must include references to the specific portions of the application (including the applicant's environmental and safety report) which the requestor or petitioner disputes and the supporting reasons for each such dispute, or, if the requestor or petitioner believes that the application fails to contain information on a relevant matter as required by law, the identification of each such failure and the supporting reasons for the requestor's or petitioner's belief. On issues arising under NEPA, a petitioner shall file contentions based on the applicant's environmental report. The petitioner can amend those contentions or file new contentions if there are data or conclusions in the NRC draft or final environmental impact statement or appraisal that differ significantly from the data or conclusions in the applicant's document. Amended or new contentions based on NRC environmental documents shall be filed and ruled upon in initial licensing proceedings in accordance with paragraph (j) of this section.

(2) The information required by paragraph (g)(1) of this section shall be filed at the time the petition or request is filed.

(3) Non-timely filing of the information required by paragraph (g)(1) of this section will not be entertained absent a determination by the Commission or the presiding officer designated to rule on the admissibility of contentions that the filing should be permitted based upon a balancing of the factors set out in paragraph (c)(3) of this section.

(4) A requestor or petitioner that fails to comply with the requirements of (g)(1) of this section with respect to at least one contention will not be permitted to participate as a party.

(h) *Response to contentions.* The applicant or licensee and any party to a proceeding may file an answer to the contentions within ten (10) days after service of the contentions. The staff may file such an answer within fifteen (15) days after service of the contentions.

(i) *Admissibility of Contentions.* The Commission or the presiding officer designated to rule on the admissibility of contentions shall refuse to admit a contention if:

(1) The contention and supporting material fail to satisfy the requirements of paragraph (g) of this section. In determining whether a genuine dispute exists on a material issue of law, fact or policy, the Commission or the presiding officer shall consider whether the information presented pursuant to paragraph (g) of this section prompts reasonable minds to inquire further as to the validity of the contention; or

(2) It appears unlikely that petitioner can prove a set of facts in support of its contention; or

(3) The contention, if proven, would be of no consequence in the proceeding because it would not entitle petitioner to

relief.

(4) A contention raising only an issue of law shall not be admitted for resolution in an evidentiary hearing, but rather, shall be decided on the basis of briefs and/or oral argument as directed by the Commission or presiding officer.

(j) *Rulings on contentions in initial licensing proceedings by the screening Atomic Safety and Licensing Board.*—(1) *Requests for hearings.* The screening Atomic Safety and Licensing Board shall rule on requests for hearings and contentions contained in the requests in all initial licensing proceedings. After providing the staff and the licensee or license applicant an opportunity to respond to the request for hearing in accordance with paragraphs (e) and (h) of this section, the screening Atomic Safety and Licensing Board shall issue an order granting or denying, in whole or in part, each request for hearing and contention therein. An order granting a request for a hearing shall specify the parties to the proceeding and the issues in controversy.

(2) *Petitions to intervene.* (i) The screening atomic safety and licensing board shall rule on petitions to intervene and the contentions contained in the petitions which are filed in all initial licensing proceedings in which a notice of hearing has been published. The screening atomic safety and licensing board shall issue an order granting or denying, in whole or in part, each petition and contention therein. An order granting a petition shall specify the parties to the proceeding and the issues admitted to the proceeding.

(ii) Issues not specified in the notice of hearing shall not be admitted to the proceeding unless the screening atomic safety and licensing board first determines that such issues should be admitted based upon a balancing of the factors set out in paragraph (c)(3) of this section.

(k)(1) An order permitting intervention and/or directing a hearing may be conditioned on such terms as the Commission or the presiding officer may direct in the interests of: (i) Restricting irrelevant, duplicative, or repetitive evidence and argument, (ii) having common interests represented by a spokesperson, and (iii) retaining authority to determine priorities and control the scope of the hearing.

(2) In any case in which, after consideration of the factors set forth in this paragraph, the Commission or the presiding officer finds that the petitioner's interest is limited to one or more of the issues involved in the proceeding, any order allowing intervention shall limit his participation accordingly.

(l) Unless otherwise expressly provided by the Commission, the granting of a petition for leave to intervene and/or hearing request does not enlarge upon the scope of issues specified in the notice of hearing or notice of opportunity for hearing.

(m) A person permitted to intervene becomes a party to the proceeding, subject to any limitations imposed pursuant to paragraph (k) of this section.

11. In § 2.714a, paragraph (a) is revised to read as follows:

§ 2.714a Appeals from certain rulings on petitions for leave to intervene and/or requests for hearing.

(a) Notwithstanding the provisions of § 2.730(f), an order of the presiding officer designated to rule on petitions for leave to intervene and/or requests for hearing may be appealed, in accordance with the provisions of this section to the Commission within ten (10) days after service of the order. The appeal shall be asserted by the filing of a notice of appeal and accompanying supporting brief. Any other party may file a brief in support of or in opposition to the appeal within ten (10) days after service of the appeal. No other appeals from rulings on petitions and/or requests for hearing shall be allowed.

* * * * *

12. In § 2.715, paragraph (c) is revised to read as follows:

§ 2.715 Participation by a person not a party.

* * * * *

(c) The presiding officer will afford representatives of an interested State, county, municipality, and/or agencies thereof, a reasonable opportunity to participate and to introduce evidence, interrogate witnesses as authorized under § 2.743 and advise the Commission without requiring the representative to take a position with respect to the issue. Such participants may also file proposed findings and exceptions pursuant to §§ 2.754 and 2.762 and petitions for review by the Commission pursuant to § 2.786. The presiding officer may require such representative to indicate with reasonable specificity, in advance of the hearing, the subject matters on which he desires to participate.

* * * * *

13. Section 2.715a is revised to read as follows:

§ 2.715a Consolidation of parties in initial licensing proceedings.

On motion or on its or his own initiative, the Commission or the presiding officer shall, after first affording the parties an opportunity to consolidate voluntarily and absent a showing by a party subject to consolidation that its rights would be prejudiced, order any parties in an initial licensing proceeding who have substantially the same interest that may be affected by the proceeding and who raise substantially the same questions, to consolidate their presentation of evidence, cross-examination, briefs, proposed findings of fact, and conclusions of law and argument. A consolidation under this section may be for all purposes of the proceeding, all of the issues of the proceeding, or with respect to any one or more issues thereof.

14. In § 2.717, paragraph (a) is revised to read as follows:

§ 2.717 Commencement and termination of jurisdiction of presiding officer.

(a) Unless otherwise ordered by the Commission, the jurisdiction of the presiding officer designated to conduct a hearing over the proceeding, including motions and procedural matters, commences when the proceeding commences. If no presiding officer has been designated, the Chief Administrative Law Judge has such jurisdiction or, if he is unavailable, another administrative law judge has such jurisciction. A proceeding is deemed to commence when a notice of hearing or a notice of opportunity for hearing pursuant to § 2.105 is issued. When a notice of hearing provides that the presiding officer is to be an administrative law judge, the Chief Administrative Law Judge will designate by order the administrative law judge who is to preside. The presiding officer's jurisdiction in each proceeding will terminate upon the expiration of the period within which the Commission may direct that the record be certified to it for final decision, of when the Commission renders a final decision, or when the presiding officer shall have withdrawn himself from the case upon considering himself disqualified, whichever is earliest.

* * * * *

15. In § 2.720, paragraph (h)(2)(ii) is revised to read as follows:

§ 2.720 Subpoenas.

* * * * *

(h) * * *

(2) * * *

(ii) In addition, a party may file with the presiding officer written interrogatories to be answered by NRC personnel with knowledge of the facts designated by the Executive Director for Operations. Upon a finding by the presiding officer that answers to the interrogatories are necessary to a proper decision in the proceeding and that answers to the interrogatories are not reasonably obtainable from any other source, such as from the Commission's Public Document Room or Local Public Document Rooms, the presiding officer may require that the staff answer the interrogatories. Such interrogatories may seek to elicit factual information reasonably related to the NRC staff's position in the proceeding, including data used, assumptions made, and analyses performed by the NRC staff. Such interrogatories shall not, however, be addressed to, or be construed to require: (A) Reasons for not using alternative data, assumptions, and analyses, where such alternative data, assumptions, and analyses were not relied on in the staff review, or (B) performance of additional research or analytical work beyond that which is needed to support the staff's position on any particular matter.

* * * * *

16. In § 2.721, paragraph (a) is redesignated as paragraph (a)(1), paragraph (a)(2) is added, paragraph (d) is revised, and paragraph (e) is added to read as follows:

§ 2.721 Atomic Safety and Licensing Boards.

(a) * * *

(2) The Commission or the Chairman of the Atomic Safety and Licensing Board Panel shall establish one or more screening atomic safety and licensing boards in the manner described in paragraph (a)(1) of this section. The screening atomic safety and licensing board shall rule on all requests for hearing and petitions for leave to intervene in initial licensing proceedings, shall rule upon and refer admissible contentions to the appropriate forum for resolution in accordance with the provisions of this chapter, may designate issues to be heard by an expert panel pursuant to § 2.722 and shall perform such other adjudicatory functions as the Commission deems appropriate.

* * * * *

(d) An atomic safety and licensing board, including a screening atomic safety and licensing board, shall have the duties and may exercise the powers of a presiding officer as granted by § 2.718 and otherwise in this part. At any time when such a board is in existence but is not actually in session, any powers which could be exercised by a presiding officer or by the Chief Administrative Law Judge may be exercised with respect to such a proceeding by the chairman of the board having jurisdiction over it. Two members of an atomic safety and licensing board constitute a quorum, if one of those members is the member qualified in the conduct of administrative proceedings.

(e) Nothing in this section limits the discretion of the Commission to designate one or more administrative law judges appointed pursuant to section 3105 of title 5 of the United States Code to preside in proceedings for granting, suspending, revoking, or amending licenses or authorizations and to perform such other adjudicatory functions as the Commission deems appropriate.

17. In § 2.722, paragraph (c) is added to read as follows:

§ 2.722 Special assistants to the presiding officer and expert panels.

* * * * *

(c) In consultation with the Panel Chairman, the presiding officer may appoint an expert panel of one, three or five experts with specific subject matter expertise. Panel members may be selected from inside or outside the Commission. Such appointments may occur at any appropriate time during the proceeding but shall, at the time of the appointment, be subject to the notice and disqualification provisions as described in § 2.704. The expert panel, with the presiding officer designated to conduct the hearing, will hear evidentiary presentations by the parties on the specific issues related to the subject matter for which the panel possesses special expertise and may examine the witnesses of the parties as a technical interrogator. The panel will advise the presiding officer of its conclusions on the specific issues through an on-the-record report. This report is advisory only; the presiding officer shall retain final authority on issues for which the expert panel was designated. In the case of an expert panel appointed to assist a screening board, the panel shall assist the board in determining whether a sufficient showing has been made to admit a particular contention(s).

18. In § 2.730 paragraph (e) is revised and paragraph (i) is added to read as follows:

§ 2.730 Motions.

* * * * *

(e) The presiding officer may dispose of written motions either by written order or by ruling orally during the course of a prehearing conference or hearing. The presiding officer should ensure that parties not present for the oral ruling are notified promptly of the order.

* * * * *

(i) *Uncontroverted motions.* If no party controverts the grounds asserted and the relief sought by the movant within the time prescribed in paragraph (c) of this section, the presiding officer shall grant the motion to the extent authorized by law.

19. Section 2.733 is revised to read as follows:

§ 2.733 Examination by experts.

Subject to the requirements of § 2.743, a party may request the presiding officer to permit a qualified individual who has scientific or technical training or experience to participate on behalf of that party in the examination and cross-examination of expert witnesses. The presiding officer may permit such individual to participate on behalf of the party in the examination and cross-examination of expert witness where it would serve the purpose of furthering the conduct of the proceeding. Upon finding: (a) That the individual is qualified by scientific or technical training or experience to contribute to the development of an adequate decisional record in the proceeding by the conduct of such examination, (b) that the individual has read any written testimony on which he intends to examine or cross-examine and any documents to be used or referred to in the course of the examination or cross-examination, and (c) that the individual has prepared himself to conduct a meaningful and expeditious examinations or cross-examination. Examination or cross-examination conducted pursuant to this section shall be limited to areas within the expertise of the individual conducting the examination or cross-examination. The party on behalf of whom such examination or cross-examination is conducted and his attorney shall be responsible for the conduct of examination or cross-examination by such individuals.

20. In § 2.740, paragraph (b)(2) is redesignated (b)(3) and new (b)(3) is reprinted for the convenience of the reader, a new paragraph (b)(2) is added, paragraph (c) is revised, and a new paragraph (g) is added to read as follows:

§ 2.740 General provisions governing discovery.

* * * * *

(b) *Scope of discovery.* * * *

(2) *Supervision of discovery.* The frequency or extent of use of the discovery methods set forth in paragraph (a) of this section may be limited by the presiding officer if he or she determines that: (i) The discovery sought is unreasonably cumulative or duplicative, or obtainable from some other formal or informal source or method that is either more convenient, less burdensome, or less expensive; (ii) the party seeking discovery has had ample opportunity by discovery in the proceeding to obtain the information sought; or (iii) the discovery is unduly burdensome or expensive, given the needs of the case, and the number and complexity of the issues in controversy. The presiding officer may act upon its own initiative or pursuant to a motion under paragraph (c) of this section to specifically limit the use of discovery, for example, the number of interrogatories any party may serve.

(3) *Trial preparation materials.* A party may obtain discovery of documents and tangible things otherwise discoverable under paragraph (b)(1) of this section and prepared in anticipation of or for the hearing by or for another party's representative (including his attorney, consultant, surety, indemnitor, insurer, or agent) only upon a showing that the party seeking discovery has substantial need of the materials in the preparation of his case and that he is unable without undue hardship to obtain the substantial equivalent of the materials by other means. In ordering discovery of such materials when the required showing has been made, the presiding officer shall protect against disclosure of the mental impressions, conclusions, opinions, or legal theories of an attorney or other representative of a party concerning the proceeding.

(c) *Protective order.* Upon motion by a party or the person from whom discovery is sought, and for good cause shown, the presiding officer may issue an order to further any of the purposes of paragraph (b) of this section, or which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense, including one or more of the following: (1) That the discovery not be had; (2) that the discovery may be had only on specified terms and conditions, including a designation of the time or place; (3) that the discovery may be had only by a method of discovery other than that selected by the party seeking discovery; (4) that certain matters may be inquired into, or that the scope of discovery be limited to certain matters; (5) that discovery be conducted with no one present except persons designated by the presiding officer; (6) that, subject to the provisions of §§ 2.744 and 2.790, a trade secret or other confidential research, development, or commercial information not be disclosed or be disclosed only in a designated way; (7) that studies and evaluations not be prepared. If the motion for a protective order is denied in whole or in part, the presiding officer may, on such terms and conditions as are just, order that any party or person provide or permit discovery.

• • • • •

(g) *Signing of discovery requests, responses, and objections.* Every request for discovery, response, or objection thereto, or motion for a protective order, shall be signed by the party or its authorized representative pursuant to § 2.713 and shall include the party's or representative's address. The signature of the attorney or other authorized representative constitutes a certification that he or she has read the request, response, objection, or motion and that it is (1) to the best of his or her knowledge, information, or belief formed after a reasonable inquiry, consistent with these rules; (2) filed in good faith and not primarily to cause delay or for any other improper purpose; and (3) insofar as discovery is requested, not unduly burdensome or expensive, given the needs of the case, its nature and complexity, and the discovery already had in the case. If a request, response, or objection is not signed it shall be of no effect. If a certification is falsely made in violation of this paragraph, the presiding officer, where appropriate and upon motion or upon its own initiative, shall impose upon the person who made the certification or the party on whose behalf the request, response, or objection is made, or both, an appropriate sanction pursuant to § 2.707 or 2.713.

21. In § 2.743, paragraphs (a), (b), (c), and (d) are revised to read as follows:

§ 2.743 Evidence.

(a) *General.* Every party to a proceeding shall have the right to present written or documentary evidence and written rebuttal evidence under oath or affirmation. Oral evidence and/or cross-examination of oral or written evidence will be allowed only as provided in paragraph (b) of this section, provided, however, that every party to a proceeding under Subpart B for modification, suspension, or revocation of a license, or imposition of a civil penalty shall have the right to present such oral evidence and rebuttal evidence and conduct such cross-examination as may be required for full and true disclosure of the facts.

(b) *Testimony and cross-examination.* (1) The parties shall submit all direct and rebuttal testimony of witnesses, in written form, unless otherwise ordered by the presiding officer upon a showing of good cause that oral presentation of the evidence on any particular fact is reasonably necessary for the efficient identification, clarification and resolution of issues.

(2) If good cause is shown the presiding officer may schedule the taking of oral evidence either by deposition or by presiding at a hearing session where a transcript of oral testimony and cross-examination is made.

(3) The presiding officer may set dates for the filing of testimony on each factual issue in controversy as follows:

(i) The license applicant shall file written direct testimony first.

(ii) All parties other than the license applicant shall file their written direct testimony on said issue not later than 20 days after the date of filing of the testimony under the preceding subsection.

(iii) All written rebuttal testimony shall be filed no later than 20 days after the date of the filing of the testimony under the preceding subsection.

(iv) The presiding officer may allow such additional rounds of testimony as deemed necessary to develop an adequate record.

(4) Written testimony shall be incorporated in the record as if read or, in the discretion of the presiding officer, may be offered and admitted in evidence as an exhibit.

(5) A party may submit a request to cross-examine on any issue of material fact by filing a written motion within 10 days after service of the written testimony concerning the issue. A party may request to cross-examine only as to issues of material fact germane to the subject matter of an admitted contention advanced by that party; provided, however, the staff, license applicant or a governmental representative admitted pursuant to § 2.715 may move to cross-examine on any admitted contention in the proceeding. The motion shall specify: (i) The disputed issue of material fact regarding which cross-examination is requested, (ii) a description in the nature of an offer of proof (see paragraph (e) of this section) of what the movant will establish by the cross-examination, (iii) a statement as to why the cross-examination will result in resolving the issue of material fact involved, (iv) a statement as to why written testimony could not establish the same points, (v) a cross-examination plan consisting of a proposed line of questions along with postulated answers which might reasonably be anticipated and which may logically lead to achieving the objective of the cross-examination, (vi) an estimate of time necessary to complete the cross-examination, and (vii) the name of the individual who shall conduct the cross-examination.

(6) Answers to a motion for cross-examination may be filed by other parties within 10 days after service of the motion.

(7) The presiding officer shall promptly issue an order granting, denying or conditioning the request for cross-examination. If the request is granted the order shall specify:

(i) The issues on which cross-examination is granted;

(ii) The person(s) allowed to conduct cross-examination, and time allowed;

(iii) The date, time and place of the hearing at which cross-examination shall take place; and

(iv) That the party sponsoring the witness(es) subject to cross-examination shall be allowed a reasonable amount of time for oral redirect examination immediately following the cross-examination.

(8) The cross-examination plan submitted to the presiding officer shall

be kept in confidence until the completion of the cross-examination, if granted, at which time it shall be physically inserted in the record.

(9) This subsection does not apply to proceedings under Subpart B for modification, suspension, or revocation of a license, or the imposition of a civil penalty.

(c) *Admissibility.* The presiding officer shall admit only relevant, material, and reliable evidence which is not unduly repetitious. Immaterial or irrelevant parts of an admissible document will be segregated and excluded if practicable.

(d) *Objections.* An objection to the admission of evidence shall briefly state the grounds of objection. Unless oral presentation of the evidence has been ordered by the presiding officer, objections to written testimony filed pursuant to paragraph (b) of this section shall be made within 10 days after service of the objectionable testimony in accordance with the provisions of § 2.730 or the objections shall be deemed waived. The presiding officer shall rule on the objections promptly. Unless otherwise ordered by the presiding officer, the filing of objections shall not extend the time for filing written testimony. The transcript or record of the proceeding shall include the objection, the grounds, and the ruling. Exception to an adverse ruling is preserved without notation on the record.

* * * * *

22. In § 2.749, paragraphs (a) and (d) are revised to read as follows:

§ 2.749 Authority of presiding officer to dispose of certain issues on the pleadings.

(a) Any party to a proceeding may move, with or without supporting affidavits, for a decision by the presiding officer in that party's favor as to all or any part of the matters involved in the proceeding. There shall be annexed to the motion a separate short and concise statement of the material facts as to which the moving party contends that there is no genuine issue to be heard. Motions may be filed at any time. Any other party may serve as an answer supporting or opposing the motion, with or without affidavits, within twenty (20) days after service of the motion. There shall be annexed to any answer opposing the motion a separate, short and concise statement of the material facts as to which it is contended that there exists a genuine issue to be heard. All material facts set forth in the statement required to be served by the moving party will be deemed to be admitted unless controverted by the statement required to be served by the opposing party. The opposing party may within ten days after service respond in writing to new facts and arguments presented in any statement filed in support of the motion. No further supporting statements or responses thereto shall be entertained.

* * * * *

(d) The presiding officer shall render the decision sought if the filings in the proceeding, depositions, answers to interrogatories, and admissions on file, together with the statements of the parties and the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a decision as a matter of law.

23. In § 2.752, paragraphs (a)(5) and (c) are revised to read as follows:

§ 2.752 Prehearing conference.

(a) * * *

(5) The setting of a hearing schedule, including a schedule for the filing of direct and rebuttal testimony; and

* * * * *

(c) The presiding officer shall enter an order which recites the action taken at the conference, the amendments allowed to the pleadings and agreements by the parties, and which limits the issues or defines the matters in controversy to be determined in the proceeding. Objections to the order may be filed by a party within five (5) days after service of the order, except that the regulatory staff may file objections to such order within ten (10) days after service. Parties may not file replies to the objections unless the presiding officer so directs. The filing of objections shall not stay the decision unless the presiding officer so orders. The presiding officer may revise the order in the light of the objections presented and, as permitted by § 2.718(i) may certify for determination to the Commission or the Atomic Safety and Licensing Appeal Board, as appropriate, such matters raised in the objections as it deems appropriate. The order shall control the subsequent course of the proceeding unless modified for good cause.

24. In § 2.754, paragraph (c) is revised to read as follows:

§ 2.754 Proposed findings and conclusions.

* * * * *

(c) Proposed findings of fact shall be clearly and concisely set forth in numbered paragraphs and shall be confined to the material issues of fact presented on the record, with exact citations to the transcript of record and exhibits in support of each proposed finding. Proposed conclusions of law shall be set forth in numbered paragraphs as to all material issues of law or discretion presented on the record. Proposed findings of fact and conclusions of law submitted by a person who does not have the burden of proof and who has only a limited interest in the proceeding shall be confined to matters which affect his interests.

25. Section 2.757 is revised to read as follows:

§ 2.757 Authority of presiding officer to regulate procedures in a hearing.

To prevent unnecessary delays or an unnecessarily large record, the presiding officer shall, consistent with § 2.743:

(a) Limit the number of witnesses whose testimony may be cumulative;

(b) Strike argumentative, repetitious, cumulative, or irrelevant evidence;

(c) Take necessary and proper measures to prevent argumentative, repetitious, or cumulative cross-examination; and

(d) Impose such time limitations on arguments as he determines appropriate, having regard for the volume of the evidence and the importance and complexity of the issues involved.

26. Section 2.758a is added to read as follows:

§ 2.758a Codification of generic factual issues resolved in initial licensing proceedings.

(a) Within 15 days after a generic factual issue(s) is resolved in an initial licensing proceeding, the presiding officer who conducted the hearing shall inform the Executive Director for Operations in writing of the factual basis upon which such issue(s) was resolved. For purposes of this section, a generic factual issue means a controverted issue of fact which is common to facilities of similar type or design and which is the subject of an evidentiary presentation before a presiding officer which is not dismissed on motion or settled by stipulation of the parties. A generic issue is considered resolved at the earlier of the time when (1) the decision of the presiding officer has become the final agency action; or (2) the opportunity for a party to seek agency review of the presiding officer's finding on the generic fact has passed and no party has sought review.

(b) Within 15 days after receipt of the notification, the Executive Director for Operations shall prepare and transmit a notice of proposed rulemaking to the Commission which is consistent with the requirements set forth in Subpart H of this part. The notice shall provide for a 45-day period for public comment.

(c) Within 45 days after the close of the public comment period and after due consideration of the comments, the Commission shall take such further action on the proposed rule as it deems appropriate.

27. Section 2.760a is revised to read as follows:

§ 2.760a Initial decision in contested proceedings on applications for facility operating licenses.

In any initial decision in a contested proceeding on an application for an operating license for a production or utilization facility, the presiding officer shall make findings of fact and conclusions of law on the matters put into controversy by the parties to the proceeding and on matters which have been determined to be the issues in the proceeding by the Commission or the presiding officer. Where the presiding officer determines that a serious safety, environmental, or common defense and security matter exists and has not been put into controversy by the parties, he or she shall certify the matter to the screening atomic safety and licensing board with an explanatory statement. This authority is to be used sparingly. The screening atomic safety and licensing board shall determine whether the matter should be examined and decided by the presiding officer or may take such other action as may be appropriate. The Executive Director for Operations, after making the requisite findings, will issue, deny, or appropriately condition the license.

28. In § 2.762, paragraph (a) is revised to read as follows:

§ 2.762 Appeals to the Commission from initial decisions.

(a) Within ten (10) days after service of an initial decision any party may take an appeal to the Commission by filing of exceptions to that decision or designated portions thereof. Exceptions submitted by a party who does not have the burden of proof or who has only a limited interest in the proceeding shall be confined to issues which that party placed in controversy or sought to place in controversy in the proceeding. Each exception shall be separately numbered and shall (1) state concisely, without supporting argumentation, the single error of fact or law which is being asserted in that exception; and (2) identify with particularity the portion of the decision (or earlier order or ruling) to which the exception is addressed. A brief in support of the exceptions shall be filed within thirty (30) days thereafter (forty (40) days in the case of the staff). The brief shall be confined to a consideration of the exceptions previously filed by the party and, with respect to each exception, shall specify, inter alia, the precise portion of the record relied upon in support of the assertion of error.

* * * * *

29. In § 2.764, paragraphs (e), (f), and (g) are removed and paragraphs (a) and (b) are revised to read as follows:

§ 2.764 Immediate effectiveness of initial decision directing issuance or amendment of construction permit or operating license.

(a) Except as provided in paragraphs (c) and (d) of this section, or as otherwise ordered by the Commission in special circumstances, an initial decision relating to the issuance or amendment of a construction permit, a construction authorization, or an operating license shall be effective immediately upon issuance unless the presiding officer finds that good cause has been shown by a party why the initial decision should not become immediately effective, subject to the review thereof and further decision by the Commission upon exceptions filed by any party pursuant to § 2.762 or upon its own motion.

(b) Except as provided in paragraphs (c) and (d) of this section, or as otherwise ordered by the Commission in special circumstances, the Executive Director for Operations, notwithstanding the filing of exceptions, shall issue a construction permit, a construction authorization, or an operating license, or amendments thereto, authorized by an initial decision, within ten (10) days from the date of issuance of the decision.

* * * * *

§ 2.785 [Removed]

30. Section 2.785 is removed.

§ 2.786 [Removed]

31. Section 2.786 is removed.

§ 2.787 [Removed]

32. Section 2.787 is removed.

§ 2.787 Composition of Atomic Safety and Licensing Appeal Boards.

[Removed]

33. In § 2.788, the section heading is revised, the introduction text of paragraph (b) is reprinted for the convenience of the reader, paragraph (b)(3) is removed, paragraph (b)(4) is redesignated paragraph (b)(3) and new (b)(3) is reprinted for the convenience of the reader, the introductory text to paragraph (e) is revised, and paragraphs (a), (c), (f), (g) and (h) are revised to read as follows:

§ 2.788 Stays of decisions of presiding officers pending review.

(a) Within ten (10) days after service of a decision or action any party to the proceeding may file an application for a stay of the effectiveness of the decision or action pending filing of and a decision on an appeal. An application for a stay may be filed with the Commission or the presiding officer.

(b) An application for a stay shall be no longer than ten (10) pages, exclusive of affidavits, and shall contain the following:

* * * * *

(3) To the extent that an application for a stay relies on facts subject to dispute, appropriate references to the record or affidavits by knowledgeable persons.

(c) Service of an applicationf or a stay on the other parties shall be by the same method, e.g. telegram, mail, as the method for filing the application with the Commission or the presiding officer.

* * * * *

(e) In determining whether to grant or deny an application for a stay, the Commission or presiding officer will consider:

* * * * *

(f) An application for a stay of a decision or action of a presiding officer may be filed before either the Commission or the presiding officer, but not both at the same time.

(g) In extraordinary cases, where prompt application is made under this section, the Commission or presiding officer may grant a temporary stay to preserve the status quo without waiting for filing of any answer. The application may be made orally provided the application is promptly confirmed by telegram. Any party applying under this paragraph shall make all reasonable efforts to inform the other parties of the application, orally if made orally.

(h) A party may file an application for a stay of a decision or action granting or denying a stay. As to a decision or action of a presiding officer, the application shall be filed with the Commission. In each case the procedures and criteria of (a)–(e) of this section shall be followed.

Appendix A [Removed]

34. Appendix A to Part 2 is removed.

PART 50—DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

35. The authority citation for Part 50 continues to read as follows:

Authority: Secs. 103, 104, 161, 182, 183, 189, 68 Stat. 936, 937, 948, 953, 954, 955, 956, as amended (42 U.S.C. 2133, 2134, 2201, 2232, 2233, 2239); Secs. 201, 202, 206, 88 Stat. 1243, 1244, 1246), unless otherwise noted. Section 50.78 also issued under Sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Sections 50.80–50.81 also issued under Sec. 184, 68 Stat. 954 as amended; (42 U.S.C. 2234). Sections 50.100–50.102 issued under Sec. 186, 68 Stat. 955; (42 U.S.C. 2236). For the purposes of Sec. 223, 68 Stat. 958, as amended; (42 U.S.C. 2273), § 50.54(i) issued under Sec. 161i 68 Stat. 949; (42 U.S.C. 2201(i)), §§ 50.70, 50.71, 50.78 issued under Sec. 161o, 68 Stat. 950, as amended; (42 U.S.C. 2201(o)) and the Laws referred to in Appendices.

36. In § 50.10, paragraphs (e)(1) and (e)(3)(i) are revised to read as follows:

§ 50.10 License required.

* * * * *

(e)(1) The Executive Director for Operations may authorize an applicant for a construction permit for a utilization facility which is subject to § 51.5(a) of this chapter, and is of the type specified in § 50.21(b)(2) or is a testing facility to conduct the following activities: (i) Preparation of the site for construction of the facility (including such activities as clearing, grading, construction of temporary access roads and borrow areas); (ii) installation of temporary construction support facilities (including such items as warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and construction support buildings); (iii) excavation for facility structures; (iv) construction of service facilities (including such facilities as roadways, paving, railroad spurs, fencing, exterior utility and lighting systems, transmission lines, and sanitary sewerage treatment facilities; and (v) the construction of structures, systems, and components which do not prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. No such authorization shall be granted unless the staff has completed a final environmental impact statement on the issuance of the construction permit as required by Part 51 of this chapter.

* * * * *

(3)(i) The Executive Director for Operations may authorize an applicant for a construction permit for a utilization facility which is subject to § 51.5(a) of this chapter, and is of the type specified in §§ 50.21(b)(2) and (3) or 50.22 or is a testing facility to conduct, in addition to the activities described in paragraph (e)(1) of this section, the installation of structual foundations, including any necessary subsurface preparation, for structures, systems and components which prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public.

* * * * *

The additional views of Chairman Palladino and Commissioner Bernthal and the separate views of Commissioners Gilinsky and Asselstine follow.

Dated at Washington, D.C. this 6th day of April, 1984.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

Chairman Palladino's Additional Views

Because there could be some misunderstanding of my intent from a reading of Commissioner Asselstine's separate views, I have the following comments.

The matters on which the Commission seeks public comment are suggestions forwarded by the Regulatory Reform Task Force. It is my understanding that, while the Task Force has not voted on whether or not to support the eventual adoption of any or all of the proposals, the Task Force agrees that the proposals are a point of departure for discussion of hearing process reform.

While the suggestions forwarded by the Task Force have received review and comment by NRC groups, they have not been published for public comment; the public has not had the opportunity to agree or disagree with either those suggestions or Commissioner Asselstine's proposals.

I recognize that some of the suggestions may not be acceptable to some members of the public or to some members of the Commission, including myself. However, I do not believe that should be the criterion for deciding whether or not to request public comment. Given the conclusion that the suggestions are a point of departure for further discussion, I do not believe that it is inappropriate for the Commission to request public comment on them.

Additional Views of Commissioner Bernthal

It should be emphasized, as the summary statement indicates, that the ideas put forward by the Regulatory Reform Task Force (RRTF) do not and are not intended to have the imprimatur of the Commission. The fact that public comments are being solicited regarding these suggestions is *not* indicative of support by the Commission, or even by a majority of the Commission, for any given proposal. Indeed, neither the RRTF nor those who reviewed its work were able to arrive at a consensus on anything other than the appropriateness of further evaluation of the possible changes to the licensing process discussed in the Draft Report. The solicitation of public comment by the Commission should signify to the public only that the Commission seeks the broadest possible informational base prior to taking any further action regarding specific proposals discussed by the RRTF. In this case I believe this procedure is entirely appropriate in view of the extensive effort that has gone into developing these proposals, and the broad interest that attaches to them.

Separate Views of Commissioner Gilinsky (Parts 2 and 50)

I agree with Commissioner Asselstine's comments on the procedural proposals being put out by the Commission majority. I also agree with his proposed reform and urge that public comments concentrate on these as they are a far sounder starting point than the package of the Commission majority. I would add that I continue to believe that the staff should cease to be a full party seeking issuance of a license, and that the Commission should replace the Appeal Board as the direct reviewer of Licensing Board decisions.

Separate Views of Commissioner Asselstine

I disagree with the majority's decision to issue for public comment these proposals for procedural changes in the nuclear power plant licensing process. These proposals, which were presented to the Commission in a November, 1982 draft report from the Chairman's Regulatory Reform Task Force (RRTF), reflect the most extreme view of licensing "reform" and, if adopted, would as a practical matter effectively eliminate public participation in the hearing process. Moreover, the process by which these proposals were developed does not support the majority's decision to proceed to issue them for comment in their present form.

As the Commission's notice makes clear, these proposals, and the accompanying explanatory discussion in the November, 1982 draft report, do not represent the views and recommendations of the Regulatory Reform Task Force. Rather, these proposals constitute nothing more than a collection of possible changes to our hearing procedures for discussion purposes. In such circumstances, the Commission should first decide which changes to its licensing procedures it believes are appropriate and beneficial, and then seek public comment on those changes. Further, any public notice of possible changes to our hearing procedures should present a full, fair and even-handed discussion of the potential advantages and disadvantages of each proposed change. The document being issued for comment by the majority today fails to meet this test. Such proposals, and the process by which they were developed, do not provide a basis for Commission development of a set of reasonable and constructive changes to the hearing process—changes that I believe are needed to improve the efficiency and effectiveness of the process and to enhance the opportunities for participation by all involved parties, including public intervenors, the utility applicants and the NRC staff.

The following proposals being issued by the majority for comment are of particular concern: the proposal to establish a higher evidentiary threshold for the admission of contentions; the proposal to require that contentions be filed at the time the request for hearing or petition for leave to intervene is filed; the proposal to limit the opportunity to amend or file contentions after the relevant staff review documents become available; the proposal to establish a single Screening Board with exclusive authority to rule on the admissibility of contentions and Licensing Board requests to pursue issues *sua sponte;* the proposal to restrict opportunities for cross-examination; the proposal to eliminate the Commission's immediate effectiveness reviews of initial licensing decisions; the proposal to eliminate the Atomic Safety and Licensing Appeal Boards; and the proposal to require the codification of all generic factual issues that are considered in individual licensing decisions.

Each of these proposals suffers from significant legal, policy or administrative disadvantages that are not readily apparent from the discussion in the document being issued by the majority. For example, the proposals for the filing of detailed support for contentions prior to any opportunity for discovery, together with the added restrictions on late-filed contentions, would impose an unfair and probably illegal burden on public intervenors. The proposal for a Screening Board would detract from the orderly continuing management of the hearing process by the Licensing Board and would remove the responsibility to rule on contentions from those best able to carry out that responsibility. The proposal to restrict opportunities for cross-examination would impose an unfair burden on public participants and would represent an improper attempt to eliminate present legal requirements for trial-type adjudicatory hearings. The proposal to eliminate Commission immediate effectiveness reviews would eliminate the only requirement for direct Commission review prior to the commencement of operation of a new plant. The proposal to eliminate the Appeal Boards would deprive the Commission of the benefits of the thorough, expert and independent reviews of Licensing Board initial decisions now provided by the Appeal Boards. The proposal to require the codification of all generic factual issues considered in an individual licensing proceeding would commit the Commission to codification even where there are no benefits to be gained by such action.

These proposals were strongly criticized by individual members of the Regulatory Reform Task Force and by members of the Senior Advisory Group, a group of senior NRC officials with extensive knowledge of, and experience with, the hearing process. In addition, the Ad Hoc Committee for Review of Nuclear Reactor Licensing Reform Proposals, a group of knowledgeable experts from outside the agency with diverse perspectives on regulatory reform issues, recommended against adoption of all but one of these proposals. Moreover, the Commission's two legal offices, either in comments on the proposals, or in previous regulatory reform evaluations, have questioned the Commission's legal authority to adopt several of these proposals.

Notwithstanding the serious legal and public policy concerns that have been raised repeatedly by members of the Task Force, the Senior Advisory Group, the Ad Hoc Committee, the Commission's legal offices and others, the draft report being issued by the Commission today paints these proposals only in the most favorable light. The discussion of the majority of the proposals is biased in favor of the proposal and fails even to mention, much less address, the countervailing legal and public policy considerations.

Despite repeated suggestions from knowledgeable individuals from within and outside the agency, the Commission has made little progress over the past two years in developing reasonable improvement in our hearing procedures. That lack of progress is directly attributable to the dogged pursuit of more radical and extreme proposals for restructuring the hearing process. Rather than continuing on this course, the Commission should: (1) Reject decisively the extreme and unwarranted proposals in this notice; (2) restructure the Task Force to assure that it will function as a source of objective advice to the Commission on the subject of regulatory reform; and (3) proceed immediately to develop appropriate rule changes and policy guidance that would result in improvements in the efficiency and effectiveness of the hearing process and in the opportunities for participation by all involved parties.

In the hope of encouraging a more sensible and constructive direction in our regulatory reform effort, I am including in these views my own suggestions for improving the hearing process. These suggestions are drawn largely from the comments and recommendations of individual members of the Regulatory Reform Task Force, the Senior Advisory Group, the Ad Hoc Committee for Review of Nuclear Reactor Licensing Reform Proposals, and from previous NRC licensing reform efforts. I would appreciate comments on whether these suggestions provide a reasonable basis for Commission development of a set of useful and appropriate changes to our hearing procedures.

In brief, I woud revise the present hearing procedures to provide for the following:

- A notice of the submission of each reactor license application. Following this notice, interested persons could notify the Commission of their interest. Such persons would then be notified of meetings between the NRC staff and the applicant, and the staff would hold periodic meetings with such interested persons to here and respond to their concerns regarding the application. A local public document room would also be established following the notice.
- A notice of opportunity for hearing would be issued following the staff's docketing review, as under present practice. The notice would require interested persons to file intervention petitions within one month. However, the only question to be considered by the Licensing Board in deciding on the petition is whether the person has standing to intervene. No contentions need be filed at this stage.
- Intervenors admitted as parties to the proceeding would be given three months after they are admitted to review available documents and to prepare contentions. Contentions filed at the end of the three-month period would be reviewed by the Licensing Board and admitted provisionally: (1) If the contention meets present Commission requirements for admissibility; (2) if it is accompanied by a statement of all significant facts known to the intervenor at that time supporting each contention, together with references to the specific sources and documents which have been or will be relied on to establish such facts; and, (3) unless the Board determines that it appears beyond doubt that the intervenor can prove no set of facts in support of its claim which would entitle it to relief. The third part of this test is modeled after the test established by the Supreme Court in *Conley* v. *Gibson*, 355 U.S. 41 (1957) for federal courts in determining whether a motion to dismiss a complaint should be granted pursuant to Rule 12 (b)(6) of the Federal Rules of Civil Procedure. In applying this part of the test, the Licensing Board would consider whether, reviewing the contention in the light most favorable to its proponent and whether every doubt resolved in the proponent's behalf, the contention states any valid claim for relief. Legal issues would be admitted and considered based upon oral argument rather than upon an adjudicatory hearing.
- A period of 4–6 months would be provided for discovery on all provisionally admitted contentions. Extensions could be granted only for good cause. The Licensing Boards would be directed by the Commission as a matter of policy to supervise closely the discovery process and to use such measures as bi-weekly telephone conference calls to manage the discovery process.
- At the close of the discovery period, the Licensing Board would rule on whether to proceed with a hearing on factual contentions. At this stage, the Board would only proceed to conduct an adjudicatory hearing on those contentions for which an intervenor has established that a genuine issue of material fact exists. In making this determination, the Board would apply the test set forth by the Court in *Independent Bankers Ass'n.* v. *Board of*

Governors, 516 F.2d 1206, 1220 n. 57 (D.C. Cir. 1975). Under this test, an intervenor need not make detailed factual allegations in order to meet the requirement that he or she raise "issues of material fact." Rather, the intervenor need only show that an "inquiry in depth" is appropriate.

- Late-filed contentions would be admitted as under the Commission's present rules. If the contention could not have been filed earlier due to the institutional unavailability (i.e., the unavailability of staff documents or emergency plans) of the information on which the contention is based, the intervenor will be presumed to have met the good cause factor in § 2.714. As a policy matter, the staff would be directed to pursue the goal of early availability of all staff documents, preferably within six months of the issuance of the notice of opportunity for hearing.
- The Licensing Boards would be granted the authority to call experts as board witnesses. As a matter of policy, the Commission would provide that parties to a proceeding could file requests with the Board to call expert witnesses on issues to be litigated in the proceeding.
- As a matter of policy, the Licensing Boards would be directed to require the preparation and use of cross-examination plans for extended cross-examination of witnesses in the hearing.
- As a matter of Commission policy, the Licensing Boards and parties to a licensing proceeding, including the NRC Staff, would be invited to recommend to the Commission generic issues considered in individual licensing proceedings which could be usefully codified.
- Hybrid hearing procedures similar to those specified in section 134 of the Nuclear Waste Policy Act of 1982 would be used on an experimental basis in a few selected cases. All parties to the proceeding would have to agree to the use of hybrid hearing procedures.

The majority of my suggestions could be adopted through the issuance of a revised Commission policy statement on the conduct of nuclear power plant licensing hearings and through some limited revisions to 10 CFR Parts 2 and 50. If adopted, I believe that changes to our hearing procedures along the lines suggested would help assure a more efficient and effective hearing process as well as one that is fair to all participants. I invite comments on this approach and would welcome the opportunity to discuss my suggestions with interested persons.

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49 FR 47034
Published 11/30/84
Comment period expires 1/29/85

10 CFR Parts 2 and 50

Revision of Backfitting Process for Power Reactors

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: Rulemaking is being initiated by the Nuclear Regulatory Commission for the purpose of establishing requirements for long-term management of its review process for the imposition of new regulatory requirements or power reactors. More specifically, the objective of the rulemaking is to address "backfitting," a process which can include both plant specific changes and generic changes as applied to one or more classes of power reactors. This rulemaking would revise 10 CFR 50.54, 50.109, 2.204, and add a conforming amendment to Appendix O. The Commission is seeking public comment on the alternatives set out in this notice with a view toward issuing a final rule.

DATE: Comment period expires January 29, 1985. Comment received after this date will be considered if it is practicable to do so but assurance for consideration cannot be given except as to comments received before this date.

ADDRESSES: Mail comments to: Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, ATTN: Docketing and Service Branch. Deliver comments to: Room 1121, 1717 H Street, NW., Washington, D.C. 20555, between 8:15 a.m. and 5:00 p.m. Copies of comments received may be examined at the NRC Public Document Room, at the same address.

FOR FURTHER INFORMATION CONTACT: James R. Tourtellotte, Chairman, Regulatory Reform Task Force, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Phone: (202) 634-3300.

SUPPLEMENTARY INFORMATION: The Commission previously published an

Advance Notice of Proposed Rulemaking on this subject at 48 FR 44217 (September 28, 1983). There the Commission announced it was initiating a rulemaking proceeding for the purpose of establishing requirements for the long-term management of its process for the imposition of new regulatory requirements on power reactors. The Commission issued an interim policy on backfitting at that time and stated its intention to replace the existing regulation (10 CFR 50.109) with a new rule. The Commission also offered a number of questions regarding revision of the backfit rule. The comment period closed October 28, 1983 and the last comment was docketed December 5, 1983.

Forty commenters filed 41 comments as follows: Utilities, 18: vendors, 4; architect engineers and service companies, 3; industry groups and associations, 3; individuals associated with industry, 3; law firms representing industry, 2; intervenors and public interest groups, 7 (2 from the same persons); federal agency, 1 (DOE).

Industry commenters varied in their approach to the Advance Notice of Proposed Rulemaking. Some were specific in their comments and suggestions while others responded in a more general manner. Among the public interest and intervenor groups, the Union of Concerned Scientists (UCS) was the only one to answer the questions and provide specific comments.

As a general principle, UCS stated that "under the Atomic Energy Act, the Commission must issue, and the industry must meet, such standards as are necessary to protect the public health and safety." From this principle they argued that cost benefit balancing is prohibited and that reliance upon the probabilistic risk assessment is invalid in the regulatory process. UCS also argued that the Commission may establish governing standards and reach decisions in one of two ways, through rulemaking or adjudication. On this basis they continued their argument by stating "the Commission exercises its rulemaking authority to establish nuclear reactor safety under 10 CFR 2.758. Such a waiver request is subject to public scrutiny in an adjudicatory proceeding and thus meets the requirements of the Administrative Procedure Act."

These positions raise interesting questions with respect to the issuance of a final rule on backfitting. In addition to comments which the public may wish to make regarding the specific sections, the Commission is interested in receiving comments on the positions outlined by UCS in association with their comments on the Advance Notice of Proposed Rulemaking. Specifically, the Commission is interested in receiving additional comments on whether cost benefit balancing is prohibited under the terms of the Atomic Energy Act and whether reliance upon probabilistic risk assessments is invalid. The Commission is also interested in views regarding the correctness of the UCS position that "the Commission exercises its rulemaking authority to establish nuclear reactor safety standards, and licensees may avoid those standards only by obtaining a waiver under 10 CFR 2.758."

A fundamental position of Industry is that backfitting should only be imposed by rule, regulation or order. Hence, backfitting would not be defined in terms of the imposition of new regulatory requirements as suggested by the RRTF and Staff proposals, but in terms of rules, regulations and orders. Accordingly, under the Industry approach backfitting of a production or utilization facility means a modification or addition required by the Commission to the facility or to the structures, systems, or components of such facility, the design thereof, or the procedures or organization required to construct or operate such facility. By defining backfitting as a modification, it would be similar to the current 50.109 approach. For standard designs, the Industry defines backfitting as the modification or addition required by the Commission to the facility or the structures, systems, or components of such facility or the design thereof after the approval has been issued.

In their October 28, 1983 comments on the Advanced Notice of Proposed Rulemaking, the AIF takes exception to the use of "regulatory requirements" as a definitional basis for backfitting. Speaking of the RRTF alternative, they stated:

> This proposed rule lacks a definition of "regulatory requirements" which, in the industry proposal, are comprised of rules, regulations, or order. The NRC view of backfitting from the "cause side" (regulatory requirements) of regulations contrasts with the industry view of backfitting from the "effects side" (modifications) of impacts. The industry version is preferred because it avoids the difficult definition of where in the infrastructure of regulatory guidance the line of defining "regulatory requirements" is drawn. Instead *any* Commission imposed change which impacts a licensed facility as defined in the industry's proposal is subjected to backfitting management controls.

The definition would also affect the grandfather clause in § 50.109(c). In this regard, Industry contends:

> Because the RRTF proposal would exempt current staff guidance, which is within its definition of "regulatory requirements," it would remove controls from a large block of requirements not previously subjected to backfit management and would exacerbate the current unsystematic process. Only applicable rules, regulations and orders should be the subject of any grandfather provisions.

Industry concern about the definition of "regulatory requirements" deserves some comment. Regulatory guides, branch technical positions, acceptance criteria and official letters are not legally enforceable to impose backfit requirements on licensees. Hence, there may understandably be some confusion as to what is meant by the term "regulatory requirement." For the purpose of backfitting regulations, "regulatory requirements" refers to any instrument or means (other than a rule, regulation, or an order to require compliance with the Commission's rules, regulations, or orders) used by the Staff to create an obligation upon licensees to change the design, construction or operation of a facility after a construction permit has been issued. The Commission has used this term only for the purpose of assuring that every means previously used by the Staff to impose an obligation to backfit is covered in the rule. There is no intent to remove controls or elevate the importance of any means previously used to impose a requirement or any type of requirement. Nevertheless, the difference between the NRC's use of "regulatory requirements" and industry's use of "rules, regulations and orders" in their respective definitions may be significant. The Commission is interested in public comments on the relative advantages and disadvantages of each definition.

The Proposal

The proposed amendment of § 50.54(f) is to assure that information requests of licensees are not unduly burdensome. Accordingly, each information request is to be evaluated prior to its issuance to assure that the burden imposed by the information request is justified in view of the potential safety significance of the issue to be addressed. Amendment of this section also provides for management control and accountability by requiring that staff evaluations be reviewed by the Executive Director for Operations prior to the issuance of the request. There appeared to be no opposition during the comment period for the Advance Notice of Proposed

Rulemaking. This section is offered once again for public comment in association with the issuance of the proposed rule.

Section 50.109 is the heart of the backfit rule proposal. Proposed § 50.109(a) requires as a condition precedent to the imposition of a backfit: (1) A "systematic and documented analysis" of certain factors listed in paragraph (d); (2) the analysis must demonstrate that the backfit will substantially increase the overall protection of the public health and safety or the common defense and security; and (3) that the increased protection will clearly exceed the direct and indirect cost of implementation of the backfit for the facility affected. Secion 50.109(a) also has an emergency exception which provides that the analysis need not be performed, however, if the Commission determines that absent immediate action to impose the backfit, the public health and safety or the common defense and security will not be adequately protected. Analysis will ultimately be required, however, as the rule further provides: Imposition of the backfit in this circumstances shall not relieve the Commission of documenting the analysis after the fact.

The standard against which proposed backfits would be measured is "substantial increase in the overall protection of the public health and safety or the common defense and security." Substantial means important or significant in a large amount, extent, or degree. Under such a standard, the Commission would not ordinarily expect that safety improvements would be required as backfits which result in an insignificant or small benefit to public health and safety or the common defense and security, regardless of the implementation costs. On the other hand, the standard is not intended to be interpreted in a manner that would result in disapprovals of worthwhile safety or security improvements having costs that are justified in view of the increased protection that would be provided.

The phrase "overall protection of the public health and safety or the common defense and security" in the proposed backfit standard also deserves some discussion. The principal purpose of requiring consideration of the overall protection that would be provided by a proposed backfit is to assure that both its negative and positive effects are taken into account in deciding whether the backfit is justified. A backfit for a part of a plant should be evaluated in light of the net increase in overall protection that the entire plant would provide as a result of the backfit, taking into account the effects it would have on other aspects of the plant. Thus, the net benefit of a backfit to the protection provided by the plant as a whole is the overriding consideration, not the benefit just to the part of the plant being backfitted.

However, the Commission does not intend use of the phrase "overall protection" in the backfit standard to signal a departure from its traditional reliance on defense in depth for protection of public health and safety. Therefore, safety improvements in one line of defense against undue risk should not be disapproved or approved based solely on the presence or absence of another line of defense to cope with the failure of the first. For example, safety improvements in the integrity of the reactor coolant system should not be dismissed merely because an emergency core cooling system has been provided to protect public health and safety with high confidence in the event that the integrity of the reactor coolant system is lost. On the other hand, such a suggested improvement may be precluded because it does not meet the substantial test, or does not increase overall protection provided by the plant due to, for example, the negative impacts on other aspects of the plant.

In the final analysis, judgment in the application of the standard will be essential in the implementation of the backfit rule.

The proposed requirement that the costs of backfits be considered and justified in view of the increased protection to public health and safety or security is based on the Commission's view that it should, in these circumstances, consider the direct costs of implementation in making safety decisions under the Atomic Energy Act.

The rule does not relieve applicants or licensees from compliance with the Commission's safety or security regulations. Accordingly, the consideration and weighing of costs contemplated by the rule is premised on the general assumption that the plant is or will be required to be in compliance with the regulations even without the backfit under construction.

Moreover, the proposed rule would not apply to requirements imposed prior to the rule's effective date. These requirements are reflected in plant specific documents and frequently include detailed measures not strictly compelled by the more general provisions of the Commission's regulations. The rule is also premised on the assumption that the plant is or will be required to be in compliance with these requirements even without the backfit.

Compliance with the Commission's regulations and requirements, as outlined above, should resolve any significant issues left unresolved at the construction permit stage of review for plants subject to the rule, and should provide a level of safety sufficient for adequate protection of the public health and safety and common defense and security under the Atomic Energy Act. Accordingly, the consideration and weighing of costs contemplated by the rule applies to backfits that are intended to result in incremental safety improvements for a plant that already provides an acceptable level of protection. In this area the Commission believes that direct and indirect implementation costs are especially relevant. Without cost as a competing consideration in these circumstances, the regulatory process takes on the characteristics of a quest for a risk-free plant—an unreasonable objective contrary to the overall intent of the Atomic Energy Act and the public interest.

Backfitting is defined as the "imposition of new regulatory requirements, or the modification of previous regulatory requirements, applicable to a facility, by means other than rulemaking after: (1) The date of issuance of the construction permit for the facility for facilities having construction permits issued after the effective date of this rule; or (2) six months before the date of docketing of the OL application for the facility for facilities having construction permits issued before the effective date of this rule; or (3) the date of issuance of the operating license for the facility for facilities having operating licenses.

Section 50.109(b) remains unchanged. Section 50.109(c), a grandfather clause, is reworded to account for regulatory requirements in the new backfit definition. Section 50.109(d) sets out seven factors to be used by the staff in its backfit analysis. Finally, § 50.109(e) explicitly recognizes the responsibility of the Executive Director for Operations to manage the Commission's backfitting program in general and requires approval of backfit analyses by the Executive Director for Operations or his designee.

As a matter of information, it may be noted that the seven factors in § 50.109(d) have precedent in existing NRC practices as seen in the Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission, NUREG–BR–0058 (hereinafter Guidelines), the approved CRGR Charter (hereinafter Charter), and the Commission's approved plan for the management of plant specific backfitting. SECY–83–321 (hereinafter NRC Manual).[1]

The seven factors to be used by the Staff for a systematic and documented analysis are listed under 50.109(d) and read as follows: "(1) Potential reduction in risk to the public from the accidental offsite release of radioactive materials; (2) potential impact on radiological exposure of facility employees; (3) installation and continuing costs associated with backfit, including the cost of facility down time for the cost of construction delay; (4) the potential safety impact of changes in plant or operational complexity including the effect on other proposed and existing requirements; (5) the estimated resource burden on the NRC associated with the proposed backfit, and the availability of such resources; (6) the potential impact of differences in facility type, design or age on the relevancy and practicality of the proposed backfit; and (7) whether the proposed backfit is interim or final and, if interim, the justification for imposing the proposed backfit on an interim basis. These seven factors are important to an understanding of the objective of the proposed change.

Although there has been some suggestion that these factors are too prescriptive, all of them are currently in use by the Commission in a similar context. The following discussion illustrates the point. Sections of the Charter, Manual and Guidelines appear to address the same general items as outlined in factors one through five of 50.109(d). In the Charter section IV(B)(iii), page 4 of the NRC Manual Chapter 0514, section 043(c)(6), the question is asked, "is the plant shut down necessary? How long?" In addition section IV(B)(v), page 4 and Chapter 0514, section 043(d)(2) requires "an assessment of cost to NRC, an assessment of cost to licensees, including resulting occupational dose increase or decrease, added plant and operational complexity and total financial costs." Finally, the Guidelines section III(B)(4)(a), page 4 requires "examples of the types of effects that could result in a cost or a benefit are listed in appendix B. The analysis should also identify the classes of persons or organizations who will receive the benefits or incur the costs, from the proposed alternatives."

Factor six requires consideration of "the potential impact of differences in facility type, design, or age on the relevancy and practicality of the proposed backfit." The Charter section IV(B)(iv), page 4 calls for "identification of category of reactors to which the generic requirement is to apply (that is . . . . all PWR's only, some vendor types, some vintage types such as BWR six and four, jet pump and non jet pump plants, etc.)." Section IV(V)(v), page 5 continues "to the extent that the category contains plants of different types or vintages, the items listed above shall be provided for each type and vintage, or justification shall be provided demonstrating that the analysis of each item is valid for all types and vintages covered." The Guidelines at section III(B)(1), page 3 also requires the staff to "identify the class or classes of licensees, reactors, or other facilities affected by the problem."

Factor seven is, "whether the backfit is interim or final, and if interim, the justification for imposing the proposed backfit on an interim basis." In the Charter at section IV(B)(iii), page 4 and the NRC Manual Chapter 0514, section 043(c)(2), it asks "is it the definitive, comprehensive position on the subject, or is it the first of a series of requirements to be issued in the future?"

Notwithstanding that drawing such parallels may suggest that the factors are generally the same as those already addressed by the Staff in other contexts and therefore not too prescriptive, contrary views may also be taken. Therefore, the Commission would like the views of the public as to whether the procedures set out in § 50.109(d) are too prescriptive, or whether they are necessary to assure that certainty is injected into the evaluation process for making a backfit determination.

It may be noted that the Commission does not intend to foreclose the possibility that the final rule may be defined to use rules, regulations and orders rather than regulatory requirements. In addition, the final rule could be applicable to rulemaking. In this regard, particular attention should be given to the following questions:

(1) Should § 50.109 also apply to backfitting imposed through rulemaking? When a modification is imposed by rule or regulation, should the affected licensee be afforded an appeal to the EDO? What is the basis for this position?

(2) Should § 50.109 limit backfitting to backfits "imposed by rule, regulation or order?" If the imposition of backfits is not limited to rule, regulation or order, what other mechanisms should be employed?

(3) Should a documented analysis of a proposed backfit come before the backfit is issued or only after an affected licensee lodges an appeal? What should the timing be for the documented analysis? What is the basis for this selection? What factors should be considered?

(4) Should backfitting be defined as the imposition of new regulatory requirements or the modification of previous requirements (the cause) or defined as a "modification or addition required by the Commission to the facility or to the structures, systems or components of such facility, the design thereof, or the procedures or organization required to construct or operate such facility" (the effect). What is the basis for this position?

(5) The industry's proposed standard for justification of a backfit is "substantial improvement in the overall safety of the plant considered over its remaining life." Is it appropriate to include the concept of "over its remaining life?" What other standard could be used?

(6) To what extent may the Commission consider costs, including economic costs in backfitting decision under the standards and processes proposed in § 50.109? What is the basis for the position stated?

Section 2.204 may be amended to require a backfitting analysis where new requirements are proposed on a licensee by reason of issuance of an amendment to the license. The Commission is interested in receiving the views of the public upon the advisability of imposing the requirements for backfitting analysis as a condition precedent to the issuance of a license amendment.

The proposal to amend 10 CFR Part 50, Appendix 0 did not appear in the ANPR. It is offered here because it appears to be necessary to conform Appendix 0 to a final rule should that rule be made by the Commission. The amendment provides that information requests to the approval holder regarding an approved design shall be evaluated prior to issuance to ensure that the burden to be imposed on respondents is justified in view of the potential safety significance of the issue to be addressed in the requested information. Each such evaluation performed by the NRC staff shall be reviewed by the Executive Director for Operations or his designee prior to issuance of the request.

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[1] The Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission, NUREG–BR–0058, may be purchased for $3.75 by calling (301) 492–9530 or by writing to the Public Services Section, Document Management Branch, Division of Technical Information and Document Control, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555; or may be purchased from the National Technical Information Services, Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161. Copies of the CRGR Charter and SECY–83–321 may be inspected or copied for a fee from the NRC Public Document Room, 1717 H Street, NW., Washington, DC. 20555.

Environmental Impact; Categorical Exclusion

The promulgation of this rule would not result in any activity affecting the environment. The rule relates only to internal NRC staff procedures.

Accordingly, the categorical exclusion in 10 CFR 51.22(c)(3) applies and no environmental impact statement or environmental assessment need be prepared.

Paperwork Reduction Act Statement

This proposed rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). Existing requirements were approved by the Office of Management and Budget, Approval Number 3150-0011.

Regulatory Flexibility Act Certification

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission hereby certifies that this proposed rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. The affected facilities are licensed under the provisions of 10 CFR 50.21(b) and 10 CFR 50.22. The companies that own these facilities do not fall within the scope of "small entities" as set forth in the Regulatory Flexibility Act or the small business size standards set forth in regulations issued by the Small Business Administration in 13 CFR Part 121.

List of Subjects

10 CFR Part 2

Administrative practice and procedure, Classified information, Confidential business information, Freedom of information, Hazardous waste, Nuclear material, Nuclear power plants and reactors, Penalties, Sex discrimination.

10 CFR Part 50

Antitrust, Classified information, Fire prevention, Incorporation by reference, Intergovernmental relations, Nuclear power plants and reactors, Penalty, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, notice is hereby given that adoption of the following amendments to 10 CFR Part 2 and 50 are contemplated.

PART 50—DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

1. The authority citation for Part 50 continues to read as follows:

Authority: Secs. 103, 104, 161, 182, 183, 186, 189, 68 Stat. 936, 937, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 1244, as amended (42 U.S.C. 2133, 2134, 2201, 2232, 2233, 2236, 2239, 2282); secs. 201, 202, 206, 88 Stat. 1242, 1244, 1246, as amended (42 U.S.C. 5841, 5842, 5846), unless otherwise noted.

Section 50.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Sections 50.57(d), 40.58, 50.91, and 50.92 also issued under Pub. L. 97-415, 96 Stat. 2071, 2073 (42 U.S.C. 2133, 2239). Section 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Sections 50.80-50.81 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Sections 50.100-50.102 also issued under sec. 186, 68 Stat. 955 (42 U.S.C. 2236).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273), §§ 50.10(a), (b), and (c), 50.44, 50.46, 50.48, 50.54, and 50.80(a) are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); §§ 50.10(b) and (c) and 50.54 are issued under sec. 161i, 68 Stat. 949, as amended (42 U.S.C. 2201(i)); and §§ 50.55(e), 50.59(b), 50.70, 50.71, 50.72, 50.73, and 50.78 are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

2. In § 50.54, paragraph (f) is revised to read as follows:

§ 50.54 Conditions of Licenses.

* * * * *

(f) The licensee shall at any time before expiration of the license, upon request of the Commission submit written statements, signed under oath or affirmation, to enable the Commission to determine whether or not the license should be modified, suspended or revoked. Each information request must be evaluated prior to issuance to ensure that the burden to be imposed on respondents is justified in view of the potential safety significance of the issue to be addressed in the requested information. Each such evaluation performed by the NRC staff must be reviewed by the Executive Director for Operations or his designee prior to issuance of the request.

* * * * *

3. §50.109, paragraphs (a) and (c) are revised and new paragraphs (d) and (e) are added to read as follows:

§ 50.109 Backfitting.

(a)(1) The Commission shall require the backfitting of a facility only when it determines, based on a systematic and documented analysis of the relevant and material factors listed in paragraph (d) of this section that there is a substantial increase in the overall protection of the public health and safety or the common defense and security to be derived from the backfit and that the direct and indirect cost of implementation for that facility are justified in view of this increase protection. This analysis need not be performed, however, if the Commission determines that immediate imposition of the backfit is required to protect the public health and safety or the common defense and security. Imposition of the backfit in this circumstance shall not relieve the Commission of documenting the analysis after the fact.

(2) As used in section, "backfitting" of a production or utilization facility means the imposition of new regulatory requirements, or the modification of previous regulatory requirements applicable to a facility, by means other than rulemaking after:

(i) The date of issuance of the construction permit for the facility for facilities having construction permits issued after [insert effective date of this amendment]; or

(ii) Six months before the date of docketing of the OL application for the facility for facilities having construction permits issued before [insert effective date of amendment]; or

(iii) The date of issuance of the operating license for the facility for facilities having operating licenses.

(3) For standard design approvals issued pursuant to Appendices M, N, and O to this part, "backfitting" means the imposition of new regulatory requirements upon the design after the approval has been issued or the modification of existing regulatory requirements by means other than rulemaking.

* * * * *

(c) Paragraph (a) of this section shall not apply to regulatory requirements imposed prior to [insert the effective date of this amendment].

(d) In reaching the determination required by paragraph (a) of this section, the Commission will consider information available concerning the following factors considered to be relevant and material, and any other information relevant and material to the proposed backfit:

(1) Potential reduction in the risk to the public from the accidental off-site release of radioactive material;

(2) Potential impact on radiological exposure of facility employees;

(3) Installation and continuing costs associated with the backfit, including the cost of facility downtime or the cost of construction delay;

(4) The potential safety impact of changes in plant or operational complexity including the effect on other proposed and existing requirements;

(5) The estimated resource burden on the NRC associated with the proposed backfit and the availability of such resources;

(6) The potential impact of differences in facility type, design or age on the relevancy and practicality of the proposed backfit; and

(7) Whether the proposed backfit is interim or final and, if interim, the justification for imposing the proposed backfit on an interim basis.

(e) The Executive Director for Operations shall be responsible for implementation of this section and all analyses required by this section shall be submitted to the Executive Director for Operations or his designee.

4. In Appendix O to 10 CFR Part 50, a new section (8) is added to read as follows:

Appendix O—Standardization of Design; Staff Review of Standard Designs

* * * * *

(8) Information requests to the approval holder regarding an approved design shall be evaluated prior to issuance to ensure that the burden to be imposed on respondents is justified in view of the potential safety significance of the issue to be addressed in the requested information. Each such evaluation performed by the NRC staff shall be reviewed by the Executive Director for Operations or his designee prior to issuance of the request.

5. The authority citation for Part 2 continues to read as follows:

Authority: Secs. 161, 181, 68 Stat. 948, 953, as amended (42 U.S.C. 2201, 2231); sec. 191, as amended, Pub. L. 84–615, 76 Stat. 408 (42 U.S.C. 2341); sec. 201, 88 Stat. 1342, as amended (42 U.S.C. 5841; 5 U.S.C. 552.

Section 2.101 as issued under secs. 53, 62, 63, 81, 103, 104, 105, 68 Stat. 930, 932, 933, 935, 936, 937, 938, as amended (42 U.S. 2073, 2092, 2093, 2111, 2133, 2134, 2135); sec. 102, Pub. L. 91–190, 63 Stat. 853, as amended (42 U.S.C. 4332); sec. 301, 88 Stat. 1248 (42 U.S.C. 5871). Sections 2.102, 2.103, 2.104, 2.105, 2.721 also issued under secs. 102, 103, 104, 105, 183, 189, 68 Stat. 936, 937, 938, 954, 955, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2233, 2239). Section 2.105 as issued under Pub. L. 97–415 96 Stat. 2073 (42 U.S.C. 2239). Sections 2.200–2.206 also issued under secs. 186, 234, 68 Stat. 955, 83 Stat. 444, as amended (42 U.S.C. 2236, 2282); sec. 206, 88 Stat. 1246 (42 U.S.C. 5846). Sections 2.300–2.309 also issued under Pub. L. 97–415, 96 Stat. 2071 (42 U.S.C. 2133). Sections 2.600–2.606 also issued under sec. 102, Pub. L. 91–190, 83 Stat. 853 as amended (42 U.S.C 4332). Sections 2.700a, 2.719 also issued under 5 U.S.C. 554. Sections 2.754, 2.760, 2.770 also issued under 5 U.S.C. 557. Section 2.790 also issued under sec. 103, 68 Stat. 936, as amended (42 U.S.C. 2133) and 5 U.S.C. 552. Sections 2.800 and 2.808 also issued under 5 U.S.C. 553. Section 2.809 also issued under 5 U.S.C. 553 and sec. 29, Pub. L. 85–256, 71 Stat. 579, as amended (42 U.S.C. 2039). Appendix A also issued under sec. 6, Pub. L. 91–580, 84 Stat. 1743 (42 U.S.C. 2135).

6. Section 2.204 is revised to read as follows:

§ 2.204 Order for modification of license.

The Commission may modify a license by issuing an amendment on notice to the licensee that the licensee may demand a hearing with respect to all or any part of the amendment within twenty (20) days from the date of the notice or such longer period as the notice may provide. If the amendment involves a backfit as defined in § 50.109(a) of this chapter, the determination required by that paragraph shall be made using the relevant and material factors set forth in § 50.109(d) of this chapter prior to issuance of the amendment unless the immediate action on items required by the amendment is needed to protect the public health and safety. The amendment will become effective on the expiration of the 20-day period during which the licensee may demand a hearing. In the event that the licensee requests a hearing, the amendment will become effective on the date specified in an order made following the hearing. When the Commission finds that the public health, safety, or interest so requires, the order may be made immediately effective.

Additional Views of Commissioner Asselstine

Backfitting is one of the most difficult and complex issues facing the Commission. The industry argues that the present process for considering and imposing changes to operating reactors and reactors under construction is informal and undisciplined, and results in the imposition of costly new requirements that are of only marginal safety benefit, or at their worst can result in a net safety loss for the facility. The principal area of concern to the industry appears to be with the changes that are required by the NRC staff to implement the general requirements of the Commission's regulations on a plant-by-plant. Typically, such changes are imposed either in response to problems identified at a particular plant or as part of the staff's ongoing effort to implement on a plant-by-plant basis more general rules adopted by the Commission.

The NRC staff and public commenters, for their part, argue that changes to existing plants and plants under construction are justified given the safety benefits of the changes and our present state of knowledge of nuclear safety, and that the NRC must retain the authority and flexi-bility to require these changes. They point out that a high standard for imposing new requirements, particularly where coupled with requirements for the extensive use of quantitative cost-benefit comparisons and lengthy and detailed written analyses, can have a strong chilling effect on the staff's efforts to develop and impose needed safety and security changes. Finally, they emphasize that excessive reliance on the monetary costs of new requirements is inconsistent with the NRC's mandate, which makes the public health and safety and the common defense and security the paramount consideration.

There is some merit in the views of both sides in the backfitting debate. After having visited a number of sites with operating plants and plants under construction, I am persuaded that there have been some instances in which the NRC staff has required changes to plants that are costly and of dubious safety value. I am also persuaded that the backfitting process has at times been too informal and has lacked the kind of supervision by more senior NRC staff members that is the hallmark of good management. Moreover, there appears to be some evidence that in a few instances a licensee has been penalized for appealing within the staff management the imposition of a proposed backfit.

At the same time, I believe that unnecessary and unjustified backfits are the exception rather than the rule, and that this agency's statutory mandate and our present state of knowledge of nuclear safety dictate the need for additional backfits now and for the foreseeable future. The simple fact is, we have a number of unresolved safety issues that must be addressed and we are still identifying new safety issues based upon the operating experience of the operating reactors. Further, the plants that are now candidates for operating licenses were given construction permits based upon very limited design information with many safety issues left unresolved. Nuclear power plant operating experience, in particular, demonstrates that there may be a continuing need for new regulatory requirements in the areas of plant design, hardware and operations. For example, the September 1984 semi-annual report by NRC's Office for Analysis and Evaluation of Operational Data (AEOD) includes as its key observations on reactor operating experience the following:

- Operational data analysis and feedback is vital, yet corrective actions taken at the individual plants are not as long-lasting or as effective as anticipated, and the basis of experience seems to be sometimes lost or forgotten with time.

- Operating experience continues to identify a wide range of system interactions.
- Operating experience indicates that a total loss of a safety system is not a rare event.
- Operating experience shows that operating practices, particularly those associated with maintenance and surveillance, are frequently deficient.
- Operating experience continues to indicate that multiple independent failures do occur.
- Operating experience has indicated component performance and reliability problems.
- Operating experience indicates that Emergency Safeguard Systems are frequently challenged.

Given this state of affairs, and as long as we are still on the learning curve regarding safety issues for the existing plants, the Commission must retain the authority and the flexibility to require changes to existing plants and plants under construction which will reduce the risk to the public posed by these facilities to a level that is as low as reasonably achievable.

What is needed in light of these legitimate competing interests is a carefully crafted backfitting rule. Such a rule should accommodate the public's interest in the prompt imposition of justified new safety and security requirements and the industry's interest in a more formal and disciplined review process for proposed new requirements to assure that they are in fact needed. Unfortunately, the Commission's proposed rule fails to provide a fair balancing of these interests. In its present form, the rule does not serve the public, the NRC staff, or the industry well.

I have four principal objections to the Commission's proposed rule. First, it seeks to impose a standard for backfitting that is subject to varying interpretation and to abuse. Under the proposed rule, the Commission could only require a backfit if it finds both that the backfit will result in a *substantial* increase in *overall* health and safety protection and that the costs of implementation for the facility are justified in view of this increased protection. This standard, particularly when read in the context of the factors to be considered in the analysis of costs and benefits, can be read as establishing a very high threshold for the imposition of a new requirement.

Depending upon how it is interpreted, this standard could be used to oppose the imposition of cost-effective safety improvements that would substantially improve the performance of a particular safety system, or that would correct a new problem identified with the performance of a safety system, because the improvement as compared to the overall safety of the plant would not lead to a "substantial" increase in "overall" protection. Similarly, this standard could be used to prevent the adoption of new requirements that would result in safety improvements because the level of improvement may not be demonstrable in quantitative terms.

Both in the rule itself and in the accompanying statement of considerations the definition of what this standard requires is extremely unclear. At best, the rule and accompanying statement present an ambiguous safety test that can be interpreted as establishing a high threshold for the imposition of a new requirement. Moreover, the Commission's standard inappropriately allocates the burden in weighing safety benefits and monetary costs by requiring the proponent of a new safety benefits outweigh the costs. As the President's Commission on the Accident at Three Mile Island recommended in its report, the burden should be upon one who opposes the imposition of a new safety requirement. That is, where additional safety improvements are not clearly outweighed by cost considerations, there should be a presumption in favor of the safety change.

Second, the list of factors to be considered under the rule in evaluating the benefits and costs of proposed backfits heavily weights the evaluation against safety and other benefits and in favor of cost considerations. Potential benefits such as the reduction in the likelihood of serious operating events and accidents, avoiding the loss of onsite property, and assuring the long-term availability of the plant's generating capacity are ignored, while every possible cost, including such questionable "costs" as the NRC resource burden, is emphasized. This emphasis in the rule on cost considerations, particularly when coupled with the high standard for imposing a new requirement, is likely to have a strong chilling effect on the staff's consideration and development of new safety requirements. Indeed, there are strong indications that similar analysis requirements now being imposed by the Committee to Review Generic Requirements (CRGR) are having just such a chilling effect on the staff's efforts to develop and promulgate new generic safety measures.

Third, the number of activities the Commission's proposed rule covers is too narrow. Rulemaking, measures to implement the Commission's regulations, and existing NRC regulatory requirements are not covered by the backfitting measure. The Commission's rule has, then, a very high standard for imposing backfits which simply does not apply to most NRC actions. This makes little sense and provides essentially no control mechanism for the NRC staff's backfitting activities which appear to be of most concern to the industry—the plant-specific changes which are required by the NRC staff to implement the Commission's further regulations.

Further, the Commission's proposed rule inappropriately includes within its scope actions of the Commission itself and the Licensing and Appeal Boards. Virtually all backfitting concerns have focused on the more informal of the NRC staff. Actions by the Boards, which are based upon a formal evidentiary record, and by the Commission, which are typically preceded by staff review, are of a different character. I am aware of no justification for extending backfitting measures to these actions.

There is one more point worth noting. The Commission has spent a substantial amount of time trying to decide how to modify one paragraph in its extensive body of regulations—i.e. that dealing with backfitting. In my view, the Commission has not spent a sufficient amount of time dealing with broader aspects of the problem we are trying to remedy. Part of the problem has been that the NRC, the industry and the public have been learning about the safety characteristics of existing nuclear plants as they have been operating. The designs for existing plants evolved at a rapid pace in the late 1960s and early 1970s without prior extensive testing of the many and various designs. Most utilities have learned the performance characteristics and particular vulnerabilities of their plants after construction of their custom-made plants has been completed. In addition, the industry has been more than willing to postpone resolution of safety issues year after year. As a result, imposition of a safety solution is more difficult, painful and costly in the long run. The NRC originally went along with this approach with all its initial benefits to the nuclear industry. But now when the NRC asks for solutions to those long-delayed problems it is charged with unnecessarily ratcheting the industry.

Further, when operation of a plant reveals a safety flaw, both the industry and the NRC respond with piecemeal fixes. No one ever steps back and looks at the big picture. The Commission's proposed rule merely perpetuates that practice. I would prefer a broader inquiry into whether there is a better approach to regulating operating plants than simply modifying our backfitting regulation. That inquiry could explore alternative regulatory philosophies, such as a major focus on utility management, reliability assurance programs, or seeking additional defense-in-depth features that would make the existing plants substantially safer and more inherently safe. I believe it is more appropriate to develop an explicit Commission regulatory philosophy for the current generation of reactors and then decide how to modify the current regulations to carry out that philosophy. Without such a new approach to regulation, I fear that we will continue to treat the symptoms, rather than the root causes, of the backfitting problem.

In sum, the Commission's proposed rule appears to be an inappropriate response to the backfitting issue. It unfairly biases cost-benefit comparisons in favor of costs and fails to recognize that the presumption should be in favor of the safety benefit. At the same time, it would not apply to many of the NRC staff's activities that should be covered by a backfitting measure. In an effort to address this problem in a fairer and more comprehensive manner, I have developed an alternative approach that is contained in the suggested alternative backfitting rule which follows. I welcome public comment on whether this alternative approach provides at least a first step toward developing a reasonable, balanced and workable approach to dealing with the backfitting problem. I would also welcome public comment on the usefulness of a broader approach to dealing with the root causes of the backfitting problem.

50.109 Backfitting (Commissioner Asselstine's Alternative Rule)

(a) *Definitions*—For the purposes of this section, "backfitting" means a change in the design, construction or operation of a facility that is imposed by the NRC staff to:

(1) Satisfy a regulatory staff position that was developed or became effective after the date of issuance of the construction permit for the facility (for facilities having construction permits issued after [insert effective date of amendment]); or

(2) Satisfy a regulatory staff position that was developed or became effective less than six months before the date of docketing of the OL application for the facility (for facilities having construction permits issued before [insert effective date of amendment]); or

(3) Satisfy a regulatory staff position that was developed or became effective after [insert effective date of amendment] for the facility (for facilities having operating licenses on [insert effective date of amendment]).

For standard design approvals issued pursuant to Appendices M, N, and O to this part, "backfitting" means a change that is imposed to satisfy a regulatory staff position that was developed or became effective after the date of issuance of the design approval.

(b) *Backfitting Standard*—The staff in accordance with the procedures specified in subsection (c), may require the backfitting of a facility if it finds that such action is needed to reduce the risk to the public health and safety or the common defense and security posed by the facility to a level that is as low as reasonably achievable. In determining whether a proposed backfit is needed, the staff shall consider any safety costs as well as the expected safety benefits of the proposed backfit. Except as provided in this subsection, the staff shall also consider the monetary costs of the proposed backfit; however, there will be a presumption in favor of the backfit unless the staff finds that the safety improvements of the backfit are clearly outweighed by monetary cost considerations. The staff shall use qualitative judgment in making cost-benefit comparisons, and may only supplement this qualitative judgment with quantitative comparisons if it finds that the safety benefits and costs can be readily and accurately described in numerical terms. The staff may not consider monetary costs in deciding whether to require the backfitting of a facility:

(1) Where the proposed backfit is necessary to assure compliance with NRC's regulations;

(2) Where the proposed backfit is being considered at the operating license stage on safety matters that were left unresolved at the time of issuance of the construction permit; and

(3) Where the proposed backfit involves a new method of implementing the Commission's regulations and previously approved implementation methods were based upon a mistake in fact.

In such instances, the staff may consider monetary costs in evaluating alternative ways for achieving the purpose of the backfit.

(c) *Review and Implementation Procedures*—

(1) The staff shall prepare a written description of each proposed backfit and a brief (i.e., not to exceed 5 pages) summary written analysis of the applicable costs and benefits of the backfit. This description and analysis shall be prepared prior to imposing the proposed backfit unless the Office Director determines that immediate imposition of the backfit is required to protect the public health and safety or the common defense and security.

(2) Each proposed generic backfit (i.e., a regulatory staff position that would impose a backfit on more than one facility) shall be reviewed by the Committee to Review Generic Requirements (CRGR). The review by the CRGR and the decision by the Executive Director for Operations (EDO) shall consider the overall costs and safety benefits of the proposed generic backfit as provided in subsection (b) and shall be based on the description and analysis required by paragraph (1) of this subsection. Affected licensees shall be informed of all approved generic backfits and shall be given the opportunity to comment on the schedule within which they are expected to be implemented. Generic backfits shall not be imposed during the review process unless the Office Director determines that the public health and safety or the common defense and security so require. For each backfit reviewed by the CRGR and disapproved by the EDO, a brief summary of the rationale for disapproval shall be prepared by the EDO and placed in the Commission's Public Document Room along with the description and analysis required by paragraph (1) of this subsection.

(3) Each proposed plant-specific backfit shall be reviewed by the Office Director, or by an individual designated by the Office Director. The affected licensee shall be afforded the opportunity to review and comment on the description and analysis required by paragraph (1) of this subsection. The staff's review and decision on the proposed backfit shall be based on the description and analysis required by paragraph (1) of this subsection, and shall consider the overall costs and safety benefits of the proposed backfit as provided in subsection (b) as well as any comments submitted by the licensee. The affected licensee shall be informed of all approved plant-specific backfits and shall be given the opportunity to comment on the schedule within which they are expected to be implemented. Plant-specific backfits shall not be imposed during the review process unless the Office Director determines that the public health and

safety or the common defense and security so require.

(d) (Current Subsection (b) unchanged).

(e) (Current Subsection (c) unchanged).

Dated at Washington, D.C. this 27th day of November, 1984.

For the Nuclear Regulatory Commission.

John C. Hoyle,
Acting Secretary.

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49 FR 50189
Published 12/27/84

10 CFR Part 2

≫ Criteria for Reopening Records in Formal Licensing Proceedings

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission is considering amending its regulations to codify NRC case law criteria for reopening a closed evidentiary record in a formal licensing proceeding and to specify further the documentary bases for motions to reopen.

The Commission believes that the current reopening criteria should be codified so that there will be no uncertainty as to what the rules require. This will facilitate proper and timely consideration of motions to reopen by the adjudicatory boards while maintaining fairness to all of the other parties to a proceeding.

DATE: Comment period expires February 11, 1985.

Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

ADDRESSES: Interested persons are invited to submit written comments and suggestions to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch. Copies of comments received may be examined at the Commission's Public Document Room at 1717 H Street, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Carole F. Kagan, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (202) 634–1493.

SUPPLEMENTARY INFORMATION: NRC case law has established decision criteria under which the evidentiary record in a closed formal licensing proceeding conducted in conformance with subpart G of 10 CFR Part 2 may be reopened to admit new evidence. Under this case law, the proponent of a motion to reopen a closed record must satisfy three decision criteria:

1. The motion must be timely, except that an exceptionally grave issue may be considered in the discretion of the presiding officer even if untimely presented.
2. It must address a significant safety or environmental issue.
3. It must be shown that a different result might be or might have been reached had the newly proffered material been considered initially. *Pacific Gas and Electric Company* (Diablo Canyon Nuclear Power Plant, Units 1 and 2), ALAB–598, 11 NRC 876, 879 (1980). *Vermont Yankee Nuclear Power Corp.* (Vermont Yankee Nuclear Power Station) ALAB–124, 6 AEC 358 (1973).

The Commission believes that the current reopening criteria should be codified so that there will be no uncertainty as to what the rules require. This will facilitate proper and timely consideration of motions to reopen by the adjudicatory boards while maintaining fairness to all of the other parties to a proceeding.

While the existing decision criteria have proved to be generally adequate, the Commission believes that there is a need for further specifications of the manner and degree of documentation required to support a motion to reopen. At least one recent motion filed before an Atomic Safety and Licensing Appeal Board was accompanied by voluminous, unorganized or poorly organized materials, with little evidence of any systematic effort by the movant to delete irrelevant or immaterial information. The task of sorting out the relevant evidence fell to the Board. Not only does this situation result in delay in considering the merits of the motion, but it also carries the risk that some piece of evidence that the proponents consider especially crucial to their allegations might be overlooked.

In order to insure timely and proper consideration of motions to reopen, the Commission is proposing that a motion to reopen be accompanied by affidavits setting forth with particularity the bases for the movant's claim. Each issue would be required to be identified separately. Allegations stemming from information provided by anonymous informants would be acceptable only if the informant were identified to the presiding officer and a request for an appropriate protective order is filed.

Paperwork Reduction Act Statement

The collection of information this proposed rule contains is exempt from the requirements of the Paperwork Reduction Act of 1980, 44 U.S.C. 3518(c)(1)(B).

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that the rule will not have a significant economic impact on a substantial number of small entities. The proposed rule imposes the additional requirement that a movant, to reopen a closed evidentiary record, file affidavits setting forth the movant's claim before the record will be reopened. Significant additional resources are not required by the rule.

List of Subjects in 10 CFR Part 2

Administrative practice and procedure, Antitrust, Byproduct material, Classified information, Environmental protection, Nuclear materials, Nuclear power plants and reactors, Penalty, Sex discrimination, Source material, Special nuclear material, Waste treatment and disposal.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and section 553 of Title 5 of the United States Code, the NRC is proposing to adopt the following amendments to 10 CFR Parts 2 and 50.

PART 2—RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS

1. The authority citation for Part 2 continues to read as follows:

Authority: Secs. 161, 181, 68 Stat. 948, 953, as amended (42 U.S.C. 2201, 2231); sec. 191, as amended, Pub. L. 87–615, 76 Stat. 409 (42 U.S.C. 2241); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); 5 U.S.C. 552.

Section 2.101 also issued under secs. 53, 62, 63, 81, 103, 104, 105, 68 Stat. 930, 932, 933, 935, 936, 937, 938, as amended (42 U.S.C. 2073, 2092, 2093, 2111, 2133, 2134, 2135); sec. 102, Pub. L. 91–190, 83 Stat. 853, as amended (42 U.S.C. 4332); sec. 301, 88 Stat. 1248 (42 U.S.C. 5871). Sections 2.102, 2.103, 2.104, 2.105, 2.721 also issued under secs. 102, 103, 104, 105, 183, 189, 68 Stat. 936, 937, 938, 954, 955, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2233, 2239). Section 2.105 also issued under Pub. L. 97–415, 96 Stat. 2073 (42 U.S.C. 2239). Section 2.200–2.206 also issued under secs. 186, 234, 68 Stat. 955, 83 Stat. 444, as amended (42 U.S.C. 2236, 2282); sec. 206, 88 Stat. 1246 (42 U.S.C. 5846). Section 2.300–2.309 also issued under Pub. L. 97–415, 96 Stat. 2071 (42 U.S.C. 2133). Section 2.600–2.606 also issued under sec. 102, Pub. L. 91–190 83 Stat. 853, as amended (42 U.S.C. 4332). Sections 2.700a, 2.719 also issued under 5 U.S.C. 554. Sections 2.754, 2.760, 2.770 also issued under 5 U.S.C. 557. Section 2.790 also issued under sec. 103, 68 Stat. 936, as amended (42 U.S.C. 2133) and 5 U.S.C. 552. Sections 2.800 and 2.808 also issued under 5 U.S.C. 553. Section 2.809 also issued under 5 U.S.C. 553 and sec. 29 Pub. L. 85–256, 71 Stat. 579, as amended (42 U.S.C. 2039). Appendix A also issued under sec. 6, Pub. L. 91–580, 84 Stat. 1473 (42 U.S.C. 2135).

2. A new § 2.743a is added to read as follows:

§ 2.743a Motions to reopen.

(a) A motion to reopen a closed record to consider additional evidence will not be granted unless the following criteria are satisfied:

(1) The motion must be timely, except that an exceptionally grave issue may be considered in the discretion of the presiding officer even if untimely presented.

(2) The motion must address a significant safety or environmental issue.

(3) The motion must demonstrate that a different result might be or might have been reached had the newly proffered evidence been considered initially.

(b) The motion must be accompanied by one or more affidavits which set forth the factual and/or technical bases for the movant's claim that the criteria of paragraph (a) of this section have been satisfied. Each of the criteria must be separately addressed, with a specific explanation of why it has been met. Where multiple allegations are involved, the movant must identify with particularity each issue it seeks to litigate and specify the allegations which it believes support the claim that that issue meets the criteria in paragraph (a) of this section.

(c) A motion predicated in whole or in part on the allegations of a confidential informant must identify, to the presiding officer, the source of the allegations and must request the issuance of an appropriate protective order.

(d) A motion to reopen which relates to a contention not previously in controversy among the parties must also satisfy the requirements for nontimely contentions in § 2.714(a)(1)(i–v).

For the Nuclear Regulatory Commission.

Dated at Washington, DC this 20th day of December 1984.

Samuel J. Chilk,

Secretary of the Commission.

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50 FR 2579
Published 1/17/85

10 CFR Part 2

Criteria for Reopening Records in Formal Licensing Proceedings

Correction

In FR Doc. 84–33644 beginning on page 50189 in the issue of Thursday, December 27, 1984, the word "Reports" appeared in the heading. The word "Records" should have appeared in its place. The heading is corrected to read as set forth above.

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50 FR 21072
Published 5/22/85
Comment period expires 7/22/85
≫Extension of comment period 8/23/85

10 CFR Part 2

Adjudications; Special Procedures for Resolving Conflicts Concerning the Disclosure or Nondisclosure of Information

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission is considering amending its rules of practice to provide special procedures for resolving conflicts concerning the disclosure or nondisclosure of information relating to an NRC investigation or inspection not yet concluded or which would reveal the identity of a confidential informant and deemed relevant and material to an adjudication. Prepared at the express direction of the Commission and intended for the sole use of NRC offices and staff, the proposed amendments apply to all NRC offices that have information relevant and material to an adjudication. The proposed amendments provide for *ex parte in camera* presentations and implement the Commission's directions in its recent statement of policy on investigations, inspections and adjudicatory proceedings.

DATES: Comments must be received on or before July 22, 1985. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

ADDRESSES: Interested persons are invited to send written comments or suggestions to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch. Comments may also be delivered to Room 1121, 1717 H Street, NW., Washington, D.C. between 8:15 a.m. and 5:00 p.m. Copies of any comments received may be examined at the NRC Public Document Room, 1717 H Street, NW., Washington, D.C. 20555.

FOR FURTHER INFORMATION CONTACT: Jane R. Mapes, Senior Regulations Attorney, Regulations Division, Office of the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555; Telephone: (301) 492–8695.

SUPPLEMENTARY INFORMATION: On September 13, 1984, the Commission published a Statement of Policy on Investigations, Inspections and Adjudicatory Proceedings (49 FR 36032–36034, September 13, 1984.) In that Statement of Policy, the Commission re-emphasized the importance and need for full disclosure of information in an adjudication so that all issues may be fully resolved and stated that:

> [A]ll parties, in NRC adjudicatory proceedings, including the NRC staff, have a duty to disclose to the boards and other parties all new information they acquire which is considered material and relevant to any issue in controversy in the proceeding. (49 FR 36032, September 13, 1984.)

At the same time, the Commission recognized the need in certain circumstances to limit disclosure to avoid compromising an NRC inspection or investigation or to protect a confidential informant. In some instances, these conflicting concerns can be reconciled by placing restrictions on the manner in which the information is disclosed, such as, for example, rescheduling consideration of certain issues during the course of a hearing or specifying the manner, time, place, or persons to whom the information may be disclosed. There are, however, certain situations in which any disclosure of information, however restricted, could affect the conduct of an inspection or investigation. In its Statement of Policy, the Commission expressed the view that in these situations the NRC staff should be required to:

> Provide the board with an explanation of the basis of its concern about disclosure and present the information to the board, *in camera*, without other parties present. (49 FR 36032 at 36034, September 13, 1984.)

The Commission also noted that:

> Because this procedure represents a departure from normal Commission procedure, it is the Commission's view that the decision should be implemented by rulemaking. (49 FR 36032 at 36033, September 13, 1984.)

The proposed rule establishes procedures, not currently included in the Commission's Rules of Practice, which may be used by all NRC offices to request the withholding of information from disclosure or the imposition of conditions under which information may be disclosed. The procedures may not be used by applicants, licensees, intervenors and others to protect or withhold their information from disclosure. These special procedures are applicable in those limited circumstances in which an NRC office is under a duty to disclose relevant and material information to a board and/or parties in an ongoing adjudication, for example, under established board notification procedures, in response to a discovery request, or as otherwise directed by the presiding officer, and it is determined that disclosure of the information without a protective order would prejudice an inspection or investigation or reveal the identity or otherwise compromise a confidential informant. Once these findings have been made, the proposed special procedures would be used by the NRC office having the information to request the imposition of conditions on disclosure or to withhold disclosure of the information.

The factors to be considered in determining whether information is eligible for a protective order imposing conditions upon or withholding disclosure of the information are set out in § 2.795e of the proposed rule and track the standards enunciated in the Statement of Policy. A protective order may either impose conditions on the manner in which the information may be disclosed or withhold disclosure of the information. In general, a protective order will be appropriate if it can be shown that the information relates to an inspection or investigation and that disclosure of the information without a protective order would be detrimental to the effective conduct of the inspection or investigation, or if it can be shown that the information would reveal the identity or otherwise compromise a confidential informant. The information need not relate solely to an ongoing inspection or investigation but may also include information on the basis of which the NRC may determine whether to initiate an inspection or investigation. After the conflict between the obligation to disclose a particular item of information and the need to impose conditions upon or withhold disclosure of that information has become apparent, the NRC office having possession of or access to the information would use the proposed special procedures as necessary to resolve the conflict.

Under the special procedures, the appropriate NRC office may move the presiding officer of the pending adjudication to grant relief from the disclosure requirement either by ordering information disclosed subject to conditions or by ordering information withheld from disclosure. For the purposes of these procedures, the term "presiding officer" includes an administrative judge, an administrative law judge, an Atomic Safety and Licensing Board, and an Atomic Safety and Licensing Appeal Board. The motion, which may be made orally or in writing, must contain a brief description of the nature of the information subject to the request and explain the relevance of the information to the pending adjudication. The motion must also state why and to what extent disclosure of the information without a protective order will compromise or impede the conduct of an NRC investigation or inspection, or reveal the identity or otherwise compromise a confidential informant. At the time the motion is made, the NRC office must notify all parties to the pending adjudication that the imposition of conditions on or the withholding of disclosure of the information has been requested. However, the information subject to the motion shall not be revealed. The NRC office must also notify the Director, Division of Rules and Records, NRC Office of Administration, who is the agency official responsible for processing Freedom of Information Act (FOIA) requests.

Upon receipt of a motion from an NRC office to impose conditions upon or to withhold disclosure of information, the presiding officer, without parties other than NRC staff present, may either rule on the motion on the basis of the information provided, conduct an *ex parte in camera* oral presentation, or request further information. Under the proposed amendments, the presiding officer is authorized to conduct an *ex parte in camera* oral presentation at any time on his or her own initiative. The presiding officer must notify all parties to the pending adjudication whenever an *ex parte in camera* oral presentation is to be held. The notice shall state the purpose, time, and place of the *ex parte in camera* oral presentation and the approximate date a ruling concerning the disclosure or nondisclosure of the information subject to the presentation may be expected. The substantive content of the information shall not be disclosed. To provide a record, a verbatim transcript will be made of each *ex parte in camera* oral presentation.

After consideration of a motion to impose conditions upon or to withhold disclosure of information, including any *ex parte in camera* oral presentation, and after finding that the information subject to the motion is both relevant and material to the pending adjudication, the presiding officer will decide, in light of the Commission policy favoring full disclosure, whether disclosure of the information without a protective order could adversely affect the NRC's ability to conduct an investigation or inspection fully and adequately or to protect identity or otherwise preserve the anonymity of a confidential informant and whether and to what extent all or part of the information should be withheld from disclosure or only disclosed subject to conditions.

If the presiding officer grants the motion, the presiding officer shall issue a protective order as requested. If the presiding officer determines that the motion should be denied in whole or in part, the presiding officer shall notify the NRC office submitting the request of the intent to order disclosure. The notice of intent to order disclosure shall specify the nature of the information to be disclosed, the terms and conditions of any proposed order and the basis for the conclusion that prompt disclosure is required. The notice of intent shall state a reasonable time by which the NRC office must submit a statement of objection or concurrence. If the NRC office concurs in the disclosure specified in the notice of intent and if the disclosure does not reveal the identity of a confidential informant, the presiding officer shall issue the order proposed. If the NRC office objects to the disclosure specified in the notice of intent and any such objection is disallowed, the presiding officer shall promptly certify the objection, the ruling disallowing the objection and the accompanying record to the Commission for *ex parte in camera* review. Every ruling requiring disclosure of the identity of a confidential informant must be certified to the Commission for review. Concurrence in such a ruling by an NRC office does not change this latter requirement.

The presiding officer shall promptly notify all parties to the pending adjudication and the Director, Division of Rules and Records, NRC Office of Administration whenever a ruling relating to the disclosure or nondisclosure of information has been issued or has been certified to the Commission for *ex parte in camera* review. A notice of certification shall state the reason for the certification, the certification date, and that, in accordance with § 2.795f, the NRC office or any other party to the adjudication may file a timely brief with the Commission. The NRC office must notify all parties to the adjudication whenever an NRC brief is filed. However, the NRC brief need not be served on the parties if to do so would reveal any of the withheld information. Within seven days after service of the notice of filing of the NRC brief, any other party to the adjudication may file a brief with the Commission. The order of the presiding officer shall be stayed pending Commission review.

The Commission shall consider any matter certified to it for review under these procedures *in camera* without parties other than the NRC staff present. The record for Commisson review shall consist of the information provided to the presiding officer *ex parte* and *in camera*, all documents filed with the presiding officer by the NRC office requesting a protective order, including any statements of concurrence or objection, the transcript of any *ex parte in camera* oral presentation, the presiding officer's notice of intent to require disclosure and the presiding officer's order. Upon its own initiative or upon request by the NRC office requesting the imposition of conditions upon the disclosure of information or the withholding of information from disclosure, the Commission may conduct an *ex parte in camera* oral presentation on any matter certified to it for review under § 2.795e. After completing its review, the Commission will decide whether to affirm, reverse, or amend the ruling.

Whenever the presiding officer or the Commission issues an order imposing conditions upon or withholding disclosure of information, the *ex parte in camera* record on which the order is based shall be deemed sealed pending further order.

The Commission does not intend these special procedures to be used to shield information properly subject to disclosure under the Freedom of Information Act (FOIA). Upon receipt of an FOIA request for release of information deemed sealed by reason of a protective order, the presiding officer or the Commission, as appropriate, will again review the nature and status of the information to determine whether all or part of the information should continue to be protected or whether all or part of the information should be released.

The NRC office at whose request the presiding officer or the Commission has issued a protective order respecting the disclosure of information shall notify the presiding officer or the Commission, as appropriate, and the Director, Division of Rules and Records, NRC Office of Administration when its objection to disclosure to the parties to the pending adjudication of all or any portion of the information subject to the order is withdrawn, when the inspection or investigation to which all or any portion of the information subject to the order relates is completed, or when it learns of any other change in the status of the protected information. Unless the information relates to the identity of a confidential informant or unless the Commission orders otherwise, information which an NRC office has consented to release may be disclosed to the parties and placed in the public record of the pending adjudication without further order. The identity of a confidential informant may only be released by order of the Commission.

Under the proposed procedures, after notice by the appropriate NRC office that an inspection or investigation has been completed or that objection to the disclosure of information has been withdrawn, whichever is earlier, and subject to certain specific limitations, the presiding officer or the Commission, as appropriate, is required to order the *ex parte in camera* record, including the verbatim transcript of any *ex parte in camera* oral presentation, included in the public record of the pending adjudication. This requirement is subject to the prohibition against inclusion in the public record of the adjudication of any part of the *ex parte in camera* record containing information pertaining to the identity of a confidential informant except pursuant to Commission order. This requirement is also subject to any other exemptions from mandatory public disclosure that may validly be claimed under the Commission's regulations, including any exemptions that may be available under 10 CFR 2.790, 9.5, 9.61 or 9.95.

Under the proposed procedures, a presiding officer may not use information subject to a protective order in making any decision in the pending adjudication unless all parties to the pending adjudication have been accorded access to the information and given an appropriate opportunity to address that information. Once all parties to the pending adjudication have been given such an opportunity, either with or without conditions, the presiding officer may use the information in reaching a decision. When information is made available only under specified conditions, a party may be unwilling to examine the information because the party does not wish to accept the conditions under which it is proffered. The fact that a party does not choose to avail itself of information to which access is permitted but only under specified conditions cannot be used to bar the presiding officer from relying on that information in reaching a decision. A presiding officer is under no obligation by reason of these special procedures to accord parties to a pending adjudication unconditional access to all information. Once the opportunity for conditional access has been provided and notwithstanding the fact that it may have been declined, the presiding officer may use the information in making a decision in the pending adjudicatory proceeding.

Minor conforming amendments to 10 CFR 2.730, 2.740 and 2.780 are also proposed.

Environmental Impact—Categorical Exclusion

The proposed amendments would amend the Commission's Rules of Practice codified in 10 CFR Part 2 and therefore meet the eligibility criteria for the categorical exclusion set forth in 10 CFR 51.22(c)(1). Accordingly, pursuant 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepered in connection with the issuance of the proposed amendments.

Paperwork Reduction Act Statement

The proposed rule is not subject to the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.) because it does not contain any information collection requirements within the meaning of section 3502(4) of that Act.

Regulatory Flexibility Act Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this rule, if adopted, will not have a significant economic impact upon a substantial number of small entities and that therefore a regulatory flexibility analysis need not be prepared. Procedural in nature, the proposed amendments provide a mechanism for the orderly resolution of conflicts respecting the obligation of NRC offices to disclose information deemed relevant and material to a pending adjudication and the need by those same offices to protect information relating to an NRC investigation or inspection or which would reveal the identity of a confidential informant. The proposed rule does not impose any obligations on entities regulated by the NRC, including any regulated entities that may fall within the definition of "small entities," as set forth in section 601(3) of the Regulatory Flexibility Act, or within the definition of "small business" as found in section 3 of the Small Business Act, 15 U.S.C. 632, or within the Small Business Size Standards in regulations issued by the Small Business Administration and codified in 13 CFR Part 121. Since the impact of the proposed rule is confined to the NRC, the proposed rule does fall within the purview of the Regulatory Flexibility Act.

List of Subjects in 10 CFR Part 2

Administrative practice and procedure, Antitrust, Byproduct material, Classified information, Environmental protection, Nuclear materials , Nuclear power plants and reactors, Penalty, Sex discrimination, Source material, Special nuclear material, Waste treatment and disposal.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended and 5 U.S.C. 553, the Nuclear Regulatory Commission is proposing to adopt the following amendments to 10 CFR Part 2.

PART 2—RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS

1. The authority citation for Part 2 is revised to read as follows:

Authority: Secs. 161, 181, 68 Stat. 948, 953,as amended (42 U.S.C. 2201, 2231); sec. 191, amended, Pub. L. 87–615, 76 Stat. 409 (42 U.S.C. 2241); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); 5 U.S.C. 552.

Sec. 2.101 also issued under secs. 53, 62, 63, 81, 103, 104, 105, 68 Stat. 930, 932, 933, 935, 936, 937, 938, as amended (42 U.S.C. 2073, 2092, 2093, 2111, 2133, 2134, 2135); sec. 102, Pub. L. 91–190, 83 Stat. 853, as amended (42 U.S.C. 4332); sec. 301, 88 Stat. 1248 (42 U.S.C. 5871). Secs. 2.102, 2.103, 2.104, 2.105, 2.721 also issued under secs. 102, 103, 104, 105, 183, 189, 68 Stat. 936, 937, 938, 954, 955, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2233, 2239). Sec. 2.105 also issued under Pub. L. 97–415, 96 Stat. 2073 (42 U.S.C. 2239). Secs. 2.200–2.206 also issued under secs. 186, 234, 68 Stat. 955, 83 Stat. 444, as amended (42 U.S.C. 2236, 2282); sec. 206, 88 Stat. 1246 (42 U.S.C. 5846). Secs. 2.300–2.309 also issued under Pub. L. 97–415, 96 Stat. 2071 (42 U.S.C. 2133). Secs. 2.600–2.606 also issued under sec. 102, Pub. L. 91–190, 83 Stat. 853 as amended (42 U.S.C. 4332). Secs. 2.700a, 2.719, and 2.795k also issued under 5 U.S.C. 554. Secs. 2.754, 2.760, 2.770 also issued under 5 U.S.C. 557. Secs. 2.790 and 2.795j also issued under sec. 103, 68 Stat. 936, as amended (42 U.S.C. 2133) and 5 U.S.C. 552. Secs. 2.800 and 2.808 also issued under 5 U.S.C. 553. Sec. 2.809 also issued under 5 U.S.C. 553 and sec. 29, Pub. L. 85–256, 71 Stat. 579, as amended (42 U.S.C. 2039). Appendix A also issued under sec. 6, Pub. L. 91–580, 84 Stat. 1473 (42 U.S.C. 2135).

2. In § 2.730, a new paragraph (i) is added to read as follows:

§ 2.730 Motions.

* * * * *

(i) The provisions of § 2.730 (a) through (h) are not applicable to motions filed pursuant to §§ 2.795a through 2.795k.

3. In § 2.740, paragraph (b)(1) is revised to read as follows:

§ 2.740 General provisions governing discovery.

* * * * *

(b) *Scope of discovery.* * * *

(1) *Gemeral.* Parties may obtain discovery regarding any matter, not privileged, which is relevant to the subject matter involved in the proceeding, whether it relates to the claim or defense of the party seeking discovery or to the claim or defense of any other party, including the existence, description, nature, custody, condition, and location of any books, documents, or other tangible things and the identity and location of persons having knowledge of any discoverable matter. For the purposes of this section, privileged matter includes information subject to a protective order issued under the special procedures in §§ 2.795a through 2.795k. In a proceeding on an application for a construction permit or an operating license for a production or utilization facility, discovery shall begin only after the prehearing conference provided for in § 2.751a and shall relate only to those matters in controversy which have been identified by the Commission or the presiding officer in the prehearing order entered at the conclusion of that prehearing conference. In such a proceeding, no discovery shall be had after the beginning of the prehearing conference held pursuant to § 2.752 except upon leave of the presiding officer upon good cause shown. It is not ground for objection that the information sought will be inadmissible at the hearing if the information sought appears reasonably calculated to lead to the discovery of admissible evidence.

* * * * *

4. In § 2.780, paragraph (a) is revised to read as follows:

§ 2.780 Ex parte communications.

(a) Except as provided under the special procedures in §§ 2.795a through 2.795k or in paragraph (e) of this section, neither (1) Commissioners, members of their immediate staffs, or other NRC officials and employees who advise the Commissioners in the exercise of their quasi-judicial functions will request or entertain off the record except from each other, nor (2) any party to a proceeding for the issuance, denial, amendment, transfer, renewal, modification, suspension, or revocation of a license or permit, or any officer, employee, representative, or any other person directly or indirectly acting in behalf thereof, shall submit off the record to Commissioners or such staff members, officials, and employees, any evidence, explanation, analysis, or advice, whether written or oral, regarding any substantive matter at issue in a proceeding on the record then pending before the NRC for the issuance, denial, amendment, transfer, renewal, modification, suspension, or revocation of a license or permit. For the purposes of this section, the term "proceeding on the record then pending before the NRC" shall include any application or matter which has been noticed for hearing or concerning which a hearing has been requested pursuant to this part.

* * * * *

5. In Subpart G, immediately following § 2.790, a new center heading and new sections 2.795a through 2.795k are added to read as follows:

Special Procedures for Resolving Conflicts Concerning the Disclosure or Nondisclosure of Information Relating to an NRC Investigation or Inspection or to the Identity of a Confidential Informant and Deemed Relevant and Material to a Pending Adjudication

§ 2.795a Applicability of special procedures; official file.

(a) Sections 2.795a through 2.795k specify procedures for resolving conflicts concerning the disclosure or nondisclosure of information relating to an investigation or inspection or to the identity of a confidential informant and deemed relevant and material to a pending adjudication. These procedures apply to all NRC offices. The procedures are to be used whenever an NRC office may be required to produce information in a pending adjudication and the NRC office having the information believes that disclosure of the information without a protective order would prejudice an investigation or inspection or reveal the identity of a confidential informant.

(b) As used in §§ 2.795a through 2.795k, the term "presiding officer" includes an administrative judge, an administrative law judge, an Atomic Safety and Licensing Board, and an Atomic Safety and Licensing Appeal Board.

(c) Unless and until publicly released, all documents required by or relating to the special procedures in §§ 2.795a through 2.795k shall bear the docket number and title of the proceeding, be marked "Not For Public Disclosure—Protected Under 10 CFR §§ 2.795a–2.795k," and transmitted to the Secretary in sealed double envelopes for deposit in the protected section of the official docket file.

§ 2.795b Requirement to disclose relevant and material information.

Information relating to an investigation or inspection or to the identity of a confidential informant and deemed relevant and material to a pending adjudication shall be disclosed to the parties to the adjudication by the NRC office having the information unless that NRC office requests the presiding officer by motion to issue a protective order imposing conditions upon the manner in which the information is disclosed or withholding the information from disclosure because disclosure without a protective order would prejudice an inspection or investigation or reveal the identity of a confidential informant.

§ 2.795c Motion for protective order; notice of motion.

(a) A motion for a protective order to impose conditions on or to withhold disclosure of information shall be addressed to the presiding officer by the NRC office having the information. At the time a motion is made and without revealing the substance of the information subject to the motion, the NRC office shall notify the parties to the adjudication and the Director, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, that a protective order to impose conditions on or to withhold disclosure of information has been requested.

(b) A motion for a protective order may be made orally or in writing, may include a request for an *ex parte in camera* oral presentation, and shall include the following information, as appropriate:

(1) A brief description of the nature of the information subject to the motion;

(2) A brief explanation why the information is relevant and material to the pending adjudication;

(3) A brief statement indicating how the information relates to an inspection or investigation and the status of the inspection or investigation, including the estimated time of completion;

(4) A statement that the information reveals the identity of a confidential informant;

(5) An explanation of the basis of the motion for a protective order to impose conditions on or to withhold disclosure of the information, including a brief explanation why and to what extent disclosure of the information without a protective order will compromise or impede the conduct of an investigation or inspection, or reveal the identity or otherwise compromise a confidential informant;

(6) The proposed relief requested.

§ 2.795d Consideration of motion by presiding officer; procedure.

(a) A motion from an NRC office for a protective order to impose conditions on or to withhold disclosure of information shall be considered by the presiding officer *in camera* without parties other than the NRC staff present.

(b) The presiding officer may require or permit the NRC office making the motion to make an *ex parte in camera* oral presentation. Attendance at an *ex parte in camera* oral presentation shall be limited exclusively to the presiding officer, to appropriate NRC personnel and to any witness appearing at the request of the NRC office or the presiding officer. The presiding officer shall promptly notify all parties to a pending adjudication when any *ex parte in camera* oral presentation will be held. The notice shall state the purpose, time, and place of the *ex parte in camera* oral presentation and the approximate date a ruling concerning the disclosure or nondisclosure of the information subject to the presentation may be expected. The substantive content of the information shall not be disclosed. If an *ex parte in camera* oral presentation is conducted, a verbatim transcript shall be made.

§ 2.795e Determination to grant or deny motion for protective order; requirement for Commission review.

(a) After consideration of a motion from an NRC office for a protective order to impose conditions on or to withhold disclosure of information, including any *ex parte in camera* oral presentation, and after finding that the information subject to the motion is both relevant and material to the pending adjudication, the presiding officer shall determine, in light of the Commission policy favoring full disclosure, whether disclosure of the information without a protective order could adversely affect the ability of the NRC to conduct an investigation or inspection fully and adequately or to protect the identity of a confidential informant and whether and to what extent all or part of the information should be withheld from disclosure or only disclosed subject to conditions.

(b) Every ruling requiring disclosure of the identity of a confidential informant shall be certified to the Commission for review. Pending Commission review, the order of the presiding officer shall be stayed.

(c)(1) If the presiding officer grants the motion, the presiding officer shall issue a protective order withholding disclosure of the information or conditioning its release, as requested.

(2) If the presiding officer determines that the motion should be denied in whole or in part, the presiding officer shall notify the NRC office submitting the motion of the intent to order disclosure. The notice of intent to order disclosure shall specify the nature of the information to be disclosed, the terms and conditions of any proposed order and the basis for the conclusion that prompt disclosure is required. The notice of intent shall state a reasonable time by which the NRC office must submit a statement of objection or concurrence.

(3) If the NRC office concurs in the disclosure specified in the notice of intent and if the disclosure does not reveal the identity of a confidential informant, the presiding officer shall issue the order proposed.

(4) If the NRC office objects to the disclosure specified in the notice of intent and any such objection is disallowed, the presiding officer shall promptly certify the objection, the ruling disallowing the objection and the accompanying record required by § 2.795f to the Commission for *ex parte in camera* review. The order of the presiding officer shall be stayed pending Commission review.

(d) The presiding officer shall promptly notify all parties to the pending adjudication and the Director, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission that a ruling relating to the disclosure or nondisclosure of information has been issued or has been certified to the Commission for *ex parte in camera* review. A notice of certification shall state the reason for the certification, the certification date, and that, in accordance with § 2.795f, any party to the adjudication may file a timely brief with the Commission.

§ 2.795f Record for Commission review; briefs.

(a) Every information disclosure ruling certified to the Commission for *ex parte in camera* review pursuant to § 2.795e will be accompanied by a record which shall consist of the information provided to the presiding officer *ex parte in camera*, all documents filed with the presiding officer by the NRC office making the motion for a protective order, including any statements of concurrence or objection, the transcript of any *ex parte in camera* oral presentation, the presiding officer's notice of intent to require disclosure and the presiding officer's order.

(b) Within ten days after the presiding officer issues an order certifying an information disclosure ruling to the Commission for *ex parte in camera* review, the NRC office may file a brief with the Commission in support of its objections to disclosure. The NRC office shall notify all parties to the adjudication that an NRC brief has been filed, but need not serve a copy of the NRC brief on the parties to the pending adjudication. Within seven days after service of the NRC notice, any party to the pending adjudication may file a brief with the Commission.

§ 2.795g Commission review.

(a) Every information disclosure ruling certified to the Commission for review under § 2.795e, together with the accompanying record and any briefs, shall be considered by the Commission *in camera* without parties other than the NRC staff present. Upon its own initiative or upon request by the NRC office making the motion for a protective order, the Commission may conduct an *ex parte in camera* oral presentation on any matter certified to it for review under § 2.795e.

(b) After review of the certified information disclosure ruling, the accompanying record and any briefs, the Commission shall decide whether to affirm, reverse, or amend the ruling. The

Commission order may include any terms or conditions deemed necessary or appropriate.

§ 2.795h Consent to disclose information; notice.

(a) The NRC office upon whose motion the presiding officer or the Commission has issued a protective order imposing conditions on or withholding the disclosure of information shall notify the presiding officer or the Commission, as appropriate, and the Director, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission when its objection to disclosure to the parties to the pending adjudication of all or any portion of the information subject to the order is withdrawn, when the inspection or investigation to which all or any portion of the information subject to the order relates is completed, or when it learns of any other change in the status of the protected information.

(b) Information which an NRC office has consented to release may be disclosed to the parties and placed in the public record of the pending adjudication without further order unless the information relates to the identity of a confidential informant or unless the Commission has ordered otherwise. The identity of a confidential informant may only be released by order of the Commission.

§ 2.795i Ex parte in camera record deemed sealed pending further order.

(a) Whenever the presiding officer under § 2.795e, or the Commission under § 2.795g, issues a protective order to impose conditions on or to withhold disclosure of information, the *ex parte in camera* record on which the order is based shall be deemed sealed pending further order.

(b) No part of any *ex parte in camera* record containing information pertaining to the identity of a confidential informant may be included in the public record of a pending adjudication or be made publicly available in any other way except pursuant to Commission order.

(c) After notice by the appropriate NRC office that an inspection or investigation has been completed or that objection to the disclosure of information has been withdrawn, whichever is earlier, and subject to the requirement in paragraph (b) of this section and to any other exemption from mandatory public disclosure that may validly be claimed under the Commission's regulations, including any exemption that may be available under § 2.790 or §§ 9.5, 9.61 or 9.95 of this chapter, the presiding officer or the Commission, as appropriate, shall order the *ex parte in camera* record included in the public record of the pending adjudication.

§ 2.795j FOIA request for release of protected information; release determination review.

(a) The Director, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, upon notice by an NRC office that information subject to an FOIA request is also subject to a protective order issued under § 2.795e or § 2.795g, shall promptly notify the presiding officer or the Commission, as appropriate.

(b) Upon notification of an FOIA request for release of protected information, the presiding officer or the Commission, as appropriate, shall review the bases for issuance of the protective order and determine, in the light of any exemptions that may validly be claimed under the provisions of the Freedom of Information Act and the Commission's regulations, whether the information in whole or in part should continue to be protected or whether and under what conditions it may be released.

§ 2.795k Prohibition against use of information subject to protective order.

Information subject to a protective order to withhold disclosure may not be used by the presiding officer in making any decision in the pending adjudication unless all parties to the pending adjudication have been accorded access to the information either with or without conditions.

Dated at Washington, D.C., this 17th day of May 1985.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

50 FR 23138
Published 5/31/85

10 CFR Part 2

Adjudications; Special Procedures for Resolving Conflicts Concerning the Disclosure or Nondisclosure of Information

Correction

In FR Doc. 85–12337 beginning on page 21072 in the issue of Wednesday, May 22, 1985, make the following corrections:

1. On page 21072, second column, the heading should appear as it does above.

2. On page 21073, second column, first complete paragraph, line twenty-seven, "information" should read "informant".

3. On the same page, third column, second complete paragraph, line eleven, "dislcosed" should read "disclosed"; in line twenty, "nor" should read "not" and "identify" should read "identity"; and in line thirty-one, "identify" should read "identity".

4. On page 21074, second column, sixth line from the bottom, "acess" should read "access".

5. On page 21075, first column **List of Subjects in 10 CFR Part 2**, fifth line, "material" should read "materials", and in the seventh line, "special" should read "Special".

§ 2.795a [Corrected]

6. On page 21076, first column, fourth line, "Appeals" should read "Appeal".

7. On the same page, first column, paragraph (c), fifth line, "preceeding" should read "proceeding".

§ 2.795e [Corrected]

8. On the same page, third column, § 2.795e (d), sixth line, "to" should appear between "relating" and "the", and in the eleventh line, "certificaiton" should read "certification".

§ 2.795f [Corrected]

9. On page 21077, first column, § 2.795f (a), tenth line, "an" should read "any".

§ 2.795j [Corrected]

10. On the same page, third column, paragraph (b), eleventh line, "should" should appear between "part" and "continue".

➤50 FR 30446
Published 7/26/85
Comment period expires 8/23/85

10 CFR Part 2

Adjudications; Special Procedures for Resolving Conflicts Concerning the Disclosure or Nondisclosure of Information; Extension of Comment Period

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule: Extension of comment period.

SUMMARY: On May 22, 1985 (50 FR 21072), the Nuclear Regulatory Commission published proposed amendments to its rules of practice to provide special procedures for resolving conflicts concerning the disclosure or nondisclosure of information relating to an NRC investigation or inspection not yet concluded or which would reveal the identity of a confidential informant and deemed relevant and material to an adjudication. The notice provided a 60-day period for public comment expiring on July 22, 1985. Two interested parties have requested a thirty day extension of time. Based on the significance of the issues involved and other factors, the NRC has decided to extend the comment period to August 23, 1985.

DATE: The extended comment period expires August 23, 1985. Comments received after that date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before that date.

ADDRESSES: Submit written comments to the Secretary of the Commission, U.S Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch. Comments may also be delivered to Room 1121, 1717 H Street, NW., Washington, D.C. between 8:15 a.m. and 5:00 p.m. Copies of comments received may be examined at the NRC Public Document Room 1717 H Street, NW., Washington, D.C. 20555.

FOR FURTHER INFORMATION CONTACT: Jane R. Mapes, Senior Regulations Attorney, Regulations Division, Office of the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555; Telephone: (301) 492-8695.

Dated at Washington, D.C., this 23rd day of July, 1985.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

UNITED STATES NUCLEAR REGULATORY COMMISSION

RULES and REGULATIONS

TITLE 10, CHAPTER 1, CODE OF FEDERAL REGULATIONS—ENERGY

PART 2

RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS

STATEMENTS OF CONSIDERATION

27 FR 377
Published 1/13/62
Effective 2/27/62

The Commission has adopted a revised 10 CFR Part 2, "Rules of Practice", governing procedure in all proceedings under the Atomic Energy Act of 1954, as amended, for granting, sustaining, revoking, or amending any license, authorization or construction permit, or application to transfer control of a licensed facility; public rule making; the disposition of appeals from decisions of contracting officers in disputes under contracts or subcontracts of the Atomic Energy Commission; and declaring a patent to be affected with the public interest or granting a patent license.

Part 2, which has been in effect since March, 1956, has been amended from time to time. On February 1, 1961, the Commission adopted "A Report on the Regulatory Program of the Atomic Energy Commission", which was the basis of a recent reorganization of its regulatory staff and functions. That Report recommended further action directed toward development of the Commission's procedural as well as substantive regulations.

In order to expedite and improve the performance of its regulatory functions, the Commission has adopted the following amendments to its regulations. The amendments are designed to expedite proceedings without sacrificing the fair and impartial consideration and adjudication of issues, and to embody the results of experience gained under the existing rules while incorporating useful provisions of the rules of practice or other regulatory agencies and of the Federal Rules of Civil Procedure.

The existing 10 CFR Part 3, "Rules of Procedure in Contract Appeals", largely incorporates by reference pertinent provisions of Part 2. The revision of Part 2 now incorporates the substance of Part 3 as a new Subpart D.

Inasmuch as this amendment relates to agency procedure and practice, the Commission has found that general notice of proposed rule making and public procedure thereon are unnecessary, and that good cause exists why this amendment should be made effective forty-five (45) days after publication in the FEDERAL REGISTER. The Commission will continue to study the problems involved in these rules with a view to making such further changes as may from time to time appear desirable. Members of the bar, commission contractors, and others are invited to submit comments and suggestions to the Commission. Comments and suggestions should be addressed to the Secretary, United States Atomic Energy Commission, Washington 25, D.C., and will be reviewed by the Commission prior to the effective date of these rules.

Pursuant to the Administrative Procedure Act and the Atomic Energy Act of 1954, as amended, the following rules are published as a document subject to codification, to be effective forty-five (45) days after publication in the FEDERAL REGISTER.

On the effective date of these rules, 10 CFR Part 3, "Rules of Practice in Contract Appeals" is repealed.

27 FR 10826
Published 11/7/62
Effective 11/7/62

The Atomic Energy Commission has revised 10 CFR Part 2, Rules of Practice, to relieve licensees in most cases from certain burdensome and generally unnecessary requirements in the filing of answers to notices of violation sent by the Commission.

Section 2.201 has required that there be incorporated in the notice of violation, which is required to be sent to any licensee prior to the institution of proceedings to revoke, modify or suspend a license, a direction that the licensee admit or deny the violation and state the reasons for the violation. The notice has also been required to include a warning that in the event of failure to reply an order may be issued to show cause why the license should not be modified, suspended or revoked or such other action taken as might be proper.

It has been found that in the case of minor technical violations, which constitute the great majority of instances in which a notice of violation is sent, these provsions are unnecessary because the violations are generally promptly corrected by licensees and further proceedings are not required. Section 2.201 has therefore been amended to eliminate the requirement that such provisions be incorporated in the notice of violation in all cases, while confirming the authority to include them in appropriate instances.

Inasmuch as this amendment relates to agency procedure and practice, the Commission has found that general notice of proposed rule making and public procedure thereon are unnecessary, and that good cause exists to make the amendment effective upon publication in the FEDERAL REGISTER.

Pursuant to the Atomic Energy Act of 1954, as amended, and the Administrative Procedure Act of 1946, the following rules are published as a document subject to codification, to be effective upon publication in the FEDERAL REGISTER.

28 FR 10151
Published 9/17/63
Effective 9/17/63

On January 16, 1963 (28 F.R. 411) the Atomic Energy Commission published for public comment proposed corrective amendments of 10 CFR Part 2.

Comments received by the Commission from interested persons have been given careful consideration, and certain of the proposed amendments have been modified. The changes are:

1. Section 2.105, paragraph (a), subparagraph (4) has been added to clarify the types of licenses and amendments which may be the subjects of public notice prior to issuance.
2. Section 2.421 has been deleted pending further consideration by the Commission.
3. Section 2.714, paragraph (a), has been revised so as to exclude Saturdays, Sundays and Holidays in the computation of time periods for filing petitions to intervene. This revision will clarify the existing language of the regulation and will avoid hardship situations when time to file a timely petition to intervene may be limited because of intervening weekends and holidays.
4. Section 2.743, paragraph (b), has been revised to clarify the language regarding the use of prepared written testimony in public proceedings.

Pursuant to the Atomic Energy Act of 1954, as amended, and the Administrative Procedure Act of 1946, the following amendments of 10 CFR Part 2 are published as a document subject to codification to be effective upon publication in the FEDERAL REGISTER.

29 FR 12829
Published 9/11/64
Effective 11/10/64

Under currently published procedures (10 CFR Part 2), the disposition of appeals from decisions of contracting officers in certain disputes arising out of contracts and certain subcontracts of the Atomic Energy Commission is a function of the Office of Hearing Examiners (10 CFR 1.15). The Commission has decided to transfer this function to a Board of Contract Appeals and to revise, simplify and make more flexible the procedures pertaining to the disposition of contract appeals. These procedures are designed to dispose of contract appeals under disputes clauses in an orderly, impartial, fair and expeditious manner. The revised procedures will be contained in 10 CFR Part 3. The principal features of the new procedures are the substitution of less formal procedures for the present procedural requirements; the use of a mandatory conference prior to hearing; the addition of an accelerated procedure for small claims and for other good causes; and the establishment of a Board which will sit in three member panels to consider, hear, and finally dispose of all appeals on behalf of the Commission.

The new rules of procedure seek to recognize the real nature of the contract appeals process, namely, a means by which an agency can take a second, top-level, independent look at the disputed actions of its authorized agents and effect any necessary revisions of such actions dictated by justice and fairness. The rules make clear that the disputes procedure is a contractual method of resolving disagreements and can be invoked only when a contract so provides.

The rules emphasize informality in order to facilitate the accomplishment of a just and inexpensive determination of an appeal without unnecessary delay. Because it is impossible to articulate a rule to fit every circumstance which could be encountered, emphasis is placed on the sound administration of these rules in specific cases.

The use of a Board as the authorized representative of the Commission to decide contract appeals is expected to provide a significant safeguard against the possibility of individual error. The inclusion of non-lawyers on the Board should afford a balanced forum with a fresh and broad insight and will tend to reduce the necessity to remand cases for resolution of technical problems. With its broadened expertise, the Board should be able to dispose finally of some problems which formerly would have been remanded.

The Chairman of the Board as the only permanent and full time member of the Board is responsible for assuring that the Board's operations are conducted in an orderly and expeditious manner. Adequate performance by the Board will depend on the active and continuing leadership of the Chairman without impinging on the freedom of the members. The Chairman will be expected to use ingenuity to effectuate management improvements in Board operations either by action of the Board itself where appropriate, or by recommendation to the Commission. In addition the Chairman will be responsible for maintaining a continuing high level of decisionary consistency.

The rules set forth the Commission's intent to vest in the Board the broadest of powers in order to enable the Board to make full and final administrative disposition of the appeal. The rules give the Board sufficient flexibility to decide appeals finally in an orderly, impartial, fair and expeditious manner. The powers specifically enumerated are not intended to be exclusive. The manner in which the Board's powers are exercised is left to the discretion of the Board. The full Board has authority to establish additional rules which would implement and supplement the rules in Part 3. Rules established by the Board will be reduced to writing and published in the FEDERAL REGISTER.

Ex parte communications with the Board are prohibited except to the extent that such communications relate to the Board's administrative functions.

The new rules include a provision to assure the contractor that he will be able to determine whether and when the contracting officer has rendered a decision which is appealable to the Board. This provision is consistent with § 1–1.318 of the recently published Federal Procurement Regulations.

The former pleading requirements have been significantly simplified to provide for the elimination of the requirement for a complaint and answer and the substitution therefor of statements of position and, at the option of each party, an argument in the form of a brief. The elimination of such formal procedural requirements is expected to simplify the administrative process and should serve to concentrate attention on the merits of a case rather than procedural matters.

The rules assure that the appellant will have access to all papers in the appeal file. The Commission wishes to emphasize the need to make all papers in the appeal file readily available to the appellant, subject to the Commission's requirements for the protection of classified and privileged information.

An important departure from prior practice is the emphasis on a mandatory conference. The new conference procedure, while having many of the attributes of a pre-hearing conference, is intended to be broader in scope than a pre-hearing conference. The purpose of the mandatory conference is to bring the parties together informally to consider the possibility of disposing of the appeal by agreement. The conference will give the parties an opportunity to discuss the case with the Board and the Board will have an active opportunity to make inquiries and attempt to narrow the issues in dispute.

The accelerated procedure may be utilized to expedite small claims and in other cases in which good cause is shown. The use of this procedure is expected to result in the expeditious handling of cases with a concomitant savings to both the appellant and the Government.

Hearings before the Board will be conducted by a full panel in order to assure that throughout the proceeding the decision-makers will have heard the entire case. Again, in the conduct of hearings, informality and Board flexibility are emphasized consistent with the need to provide an appropriate record for judicial review.

Because these rules relate solely to agency practice or procedure, the Commission has found that notice of proposed rule making, and public procedures thereon are unnecessary. Appeals filed prior to the effective date of 10 CFR Part 3 shall be handled under the procedures and delegations of authority in effect on the date the appeal is filed unless, at the option of the appellant, application of the procedures in Part 3 is requested.

Accordingly, the following amendments of 10 CFR Parts 1 and 2 and a new Part 3 are published as documents subject to codification to be effective 60 days after publication in the FEDERAL REGISTER.

31 FR 4339
Published 3/12/66
Effective 4/11/66

Review of Initial Decision

On November 5, 1965, the Atomic Energy Commission published in the FEDERAL REGISTER (30 F.R. 14014) proposed amendments to its regulations which would eliminate, in licensing and compliance proceedings, the procedure for Commission review of initial decisions by the filing of petitions for review, whose granting is discretionary, and substitute appeals as of right by the filing of exceptions by the parties.

All interested persons were invited to submit written comments and suggestions for consideration in connection with the proposed amendments within 60 days after publication of the notice of proposed rule making in the FEDERAL REGISTER. Upon consideration of the material submitted in response to the notice of proposed rule making and other factors involved, the Commission has decided to adopt the amendments set forth below, which, except as noted, are the same as those set out in the notice of the proposed rule making.

The amendments to 10 CFR Part 2, "Rules of Practice," permit appeals as of right from initial decisions by the filing of exceptions. Amendments are also made to related sections of Part 50, "Licensing of Production and Utilization Facilities," and Part 115, "Procedure for Review of Certain Nuclear Reactors Exempted from Licensing Requirements," to reflect the changes in Part 2. The amendments do not affect the Commission's opportunity to review initial decisions within 45 days on its own motion. The principal purpose of the amendments is not to encourage the taking of appeals from initial decisions, but rather to expedite the Commission's decisional process by the elimination of procedural requirements—the petition for review and Commission ruling on the petition—which have not proved necessary.

The amendments to Part 2, as proposed in the notice of proposed rule making, specified (§ 2.762) that exceptions might be filed within 20 days after service of the initial decision and a party might file a brief in support of his exceptions, or in opposition to the exceptions filed by another party, within such period after service of the initial decision as might be fixed therein. The amendment of § 2.762 set forth below provides that both exceptions and the supporting brief of the excepting party shall be filed within 20 days after service of the initial decision. Briefs in opposition to exceptions or in support of exceptions filed by another party may be filed within 10 days after the service of exceptions. It is expected that a general requirement for exceptions and supporting briefs to be filed together, by a specified day, and for answering briefs also to be filed by a specified day, will serve to expedite and shorten the Commission's adjudicatory process. If in any case good cause can be shown for extending the specified period, the Commission may, under § 2.711 of Part 2, grant such extensions.

Pursuant to the Atomic Energy Act of 1954, as amended, and the Administrative Procedure Act of 1946, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Parts 2, 50, and 115, are published as a document subject to codification, to be effective thirty (30) days after publication in the FEDERAL REGISTER.

31 FR 4389
Published 3/15/66
Effective 4/14/66

Service of Papers Upon Attorney

Public Law 89–332, 79 Stat. 1281, which was approved November 8, 1965, provides that members of the bar in good standing may represent other persons before federal agencies.

Section 2 of P.L. 89–332 provides that:

> When any participant in any matter before an agency is represented by a person qualified pursuant to subsection (a) or (b) of section 1, any notice or other written communication required or permitted to be given to such participant in such matter shall be given to such representative in addition to any other service specifically required by statute * * *.

This section makes mandatory service of papers upon the attorney representing a party.

Section 2.712(b) of 10 CFR Part 2, which pertains to service of papers in Commission adjudicatory proceedings involving licensing and compliance, provides, in part, that: "When a party has appeared by attorney, service *may* be made upon the attorney of record." (Emphasis supplied.)

In order to make the Commission's rules of practice in licensing and compliance proceedings consistent with P.L. 89–332, the Commission has adopted the amendment to § 2.712(b) of Part 2 published below, making service upon the attorney of a party mandatory.

Inasmuch as this amendment relates to agency procedure and practice, the Commission has found that general notice of proposed rule making and public procedure thereon are unnecessary.

Accordingly, the following amendment to 10 CFR Part 2 is published as a document subject to codification to be effective 30 days after publication in the FEDERAL REGISTER.

31 FR 12774
Published 9/30/66
Effective 10/30/66

Miscellaneous Amendments

On January 21, 1966, the Atomic Energy Commission published for comment (1) proposed amendments of its rules of practice, 10 CFR Part 2, (2) a proposed statement of general policy to be appended to that part and (3) miscellaneous proposed amendments of Parts 2, 50, 55, and 115 (31 F.R. 832). The proposed amendments were expected to expedite the Commission's facility licensing procedures and clarify certain provisions in existing regulations. The Commission also published on the same date, under separate notices, proposed amendments to Part 2 relating to intra-agency communications in regulatory adjudications (31 F.R. 830) and a proposed amendment to Part 2 to state precisely when the jurisdiction of a presiding officer terminates (31 F.R. 831).

The proposed amendments to Part 2 in all three notices and the proposed policy statement reflected, in general, several of the recommendations made by a seven-member Regulatory Review Panel, appointed by the Commission to study (1) the programs and procedures for licensing and regulation of reactors and (2) the decision-making process in the Commission's regulatory program. The Panel's report included a number of recommendations in both areas, particularly in respect to the conduct of "uncontested" licensing proceedings at the construction permit stage.

All interested persons were invited to submit written comments and suggestions for consideration in connection with all of the proposed amendments within 60 days after publication of the notices of proposed rule making in the FEDERAL REGISTER. After careful consideration of the comments received, the Commission has decided to adopt the amendments set forth below, which except as noted, are the same as those set out in the notices of proposed rule making.

Amendments to Part 2—Intra-agency communications in initial licensing proceedings. The following amendments to §§ 2.4, 2.719, and 2.780 permit consultation and communications between Commissioners and presiding officers (hearing examiners and atomic safety and licensing boards) on the one hand, and the regulatory staff, on the other hand, in initial licensing proceedings other than contested proceedings. Such communication and consultation is also permitted with the staff other than the regulatory staff upon the initiative of the Commissioners. A contested proceeding is defined as one in which there is a controversy between the regulatory staff and the applicant concerning the issuance of the license or any of the terms and conditions thereof or in which a petition to intervene in opposition to the application has been granted or is pending before the Commission. In addition, the following amendments permit presiding officers to consult, in initial licensing proceedings other than contested proceedings, with members of the panel appointed by the Commission from which members of atomic safety and licensing boards are drawn. However, the statement of general policy set out below (Appendix A to Part 2) includes a statement to the effect that it is expected that such consultation will relate to specific technical matters rather than to matters of broad policy.

The proposed amendments published at 31 F.R. 330 would not have required that communication and consultation between the Commissioners and the staff other than the regulatory staff, in uncontested initial licensing proceedings, be upon the initiative of the Comsioners. Further, the proposed amendments would have permitted Commissioners to consult, in contested initial licensing proceedings, with staff who had not participated in the hearing as witness or counsel, and would have permitted presiding officers to consult with the entire Commission staff in uncontested initial licensing proceedings, and in both contested and uncontested initial licensing proceedings, with the panel from which atomic safety and licensing boards are appointed. Since the Commission appointed a new Regulatory Review Panel on April 4, 1966, to study the conduct of contested proceedings, it has been decided to postpone any amendments to the Commission's rules relating to intra-agency communications in such proceedings until the recommendations of that Panel have been received. Limiting consultation by presiding officers to the regulatory staff will afford them access to those members of the staff who have the greatest familiarity with the subject matter of the proceeding.

The changes will in no way lessen the fairness or objectivity which characterize the Commission's present decision-making process. If either a final or an initial decision rests on fact or opinion obtained as a result of any communication authorized by the amendments, the substance of the communication is required to be made a matter of public record in the proceeding and opportunity for rebuttal afforded to any party on timely request, thus assuring that decisions will be made on the basis of the public record in the proceeding.

Termination of jurisdiction of presiding officers. The amendment of § 2.717(a) set out below provides that the jurisdiction of presiding officers in adjudicatory proceedings shall terminate when the initial decision becomes the final action of the Commission in the absence of review, or when the Commission, after review, renders a final decision, or when the presiding officer withdraws from the case upon considering himself disqualified, whichever is earliest. The amendment makes clear that presiding officers, who exercise quasi-judicial functions, would have no authority or responsibility to take any action after that time. The amended paragraph is the same as that published for comment at 31 F.R. 831.

Notice of hearing. The amendment of § 2.104 which follows adds a new paragraph (b) to set out the issues which will be specified in the notice of hearing on applications for a construction permit for a facility under section 103 or section 104 b. of the Atomic Energy Act of 1954, as amended (the Act), or for a testing facility under section 104 c. of the Act. If such a proceeding is not contested, a de novo evaluation of the application would not be conducted, and the board would determine whether the application and the record of the proceeding contain sufficient information, and the review of the application by the Commission's regulatory staff has been adequate, both to support the findings proposed to be made by the Director of Regulation, which are necessary under the Act and the Commission's regulations for the issuance of a provisional construction permit, and the issuance of the provisional construction permit as proposed by the Director of Regulation. If such a proceeding is contested, the board will decide all matters in controversy, and make the findings on the issues specified in the notice of hearing for a contested proceeding.

Except for minor editorial changes, § 2.104(b) is the same as the proposed paragraph published for comment at 31 F.R. 832.

Technically qualified alternates for atomic safety and licensing boards. The amendment of § 2.721 sets out the procedure which will be followed by the Commission in designating a technically qualified alternate for an atomic safety and licensing board and the effect of such designation. The amendment specifies that if a technically qualified member of a board becomes unavailable before the hearing commences, the board may constitute the alternate as a member of the board by notifying the Commission and the alternate.

Effectiveness of initial decisions. Section 2.764 has been amended to provide that, except where good cause has been shown by a party why the initial decision should not become immediately effective, an initial decision which directs the issuance or amendment of a construction permit or authorization will be effective immediately, without the necessity of filing a motion for expedited effectiveness, subject to Commission review. The amendment also provides for issuance of the permit authorized within 10 days from the effective date of the initial decision. The text of amended § 2.764 is the same as that of the proposed amendment published for comment at 31 F.R. 832.

Statement of general policy—appendix A to Part 2. Licensing hearings involving the construction and operation of nuclear reactors and other production and utilization facilities are ordinarily conducted by atomic safety and licensing boards whose establishment by the Commission was authorized by section 191 of the Act. The Commission has authorized such boards to conduct public hearings and make initial decisions in proceedings relating to the granting, suspending, revoking, or amending of licenses or authorizations issued by the Commission. Rules applicable to licensing proceedings conducted by boards (and by hearing examiners) are set forth in 10 CFR Part 2.

The statement of general policy set out below (Appendix A to Part 2) explains the procedures to be followed in the conduct by atomic safety and licensing boards of proceedings involving applications for construction permits on which the Act requires a hearing.

The statement of general policy adopted is the same as that published for comment at 31 F.R. 832 except for minor editorial changes in sections I(d), II (Prehearing Conference), III(b)(6), (g), VI(b)(1)(c), and (d), the addition of a sentence in section I, that the notice of hearing will ordinarily announce the date and place of the prehearing conference, and the addition of new sections V(c) and VI(g) relating to intra-agency communications.

Amendments to Parts 50, 55, and 115. The Commission has adopted certain minor or clarifying amendments of 10 CFR Parts 50 and 115 with respect to (1) the findings necessary to support the issuance of a provisional construction permit or authorization and (2) the terms used to designate the documents which are now termed (a) the "hazards report" submitted by applicants for permits or licenses under Part 50 or authorizations under Part 115 and (b) the "hazards analysis" prepared by the Commission's regulatory staff.

Sections 50.35(a) and 115.24(a), which authorize issuance of a provisional construction permit or authorization upon the Commission's making certain findings, have been amended to clarify the point that certain design and technical information need not be submitted by the applicant until the operating license stage. Except for minor editorial changes in §§ 50.35(a)(3) and 115.24(a)(3), the text of the amended paragraphs is the same as that of the proposed amendments published for comment at 31 F.R. 832.

In addition, the Commission has amended Parts 50 and 115 (and Parts 2 and 55) to substitute the term "safety analysis report" for "hazards summary report" and "safety analysis" for "hazards analysis" (or the equivalent) where they appear.

Pursuant to the Atomic Energy Act of 1954, as amended, and the Administrative Procedure Act of 1946, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Parts 2, 50, 55, and 115, are published as a document subject to codification, to be effective thirty (30) days after publication in the Federal Register.

31 FR 16309
Published 12/21/66
Effective 1/20/67

Establishment of Chairman of Atomic Safety and Licensing Board Panel

The Atomic Energy Commission is authorized under section 191 of the Atomic Energy Act of 1954, as amended, to establish one or more atomic safety and licensing boards, each composed of three members, two of whom shall be technically qualified and one of whom shall be qualified in the conduct of administrative proceedings, to conduct public hearings and to make intermediate or final decisions in administrative proceedings relating to the granting, suspending, revoking or amending of licenses or authorizations under the Act.

The Commission has selected board members from a panel of qualified persons appointed pursuant to section 191 to conduct hearings on applications for certain facility licenses, and to render initial decisions in such cases. The atomic safety and licensing boards, as the "presiding officer" in such proceedings, exercise the same powers as are accorded hearing examiners under section 7 of the Administrative Procedure Act (5 U.S.C. 1006).

The Commission has concluded that the activities of the atomic safety and licensing boards (the boards) can be better coordinated, the conduct of its licensing hearings expedited, and its administrative processes improved, by the establishment of a permanent Chairman and a Vice Chairman of the Atomic Safety and Licensing Board Panel (the panel). The Chairman will be a full-time employee of the Commission. Such a Chairman and Vice Chairman will, of course, as members of the panel, be available to serve as members of an atomic safety and licensing board from time to time. In addition, the Chairman will have the functions of (1) coordinating and supervising the activities of the boards; (2) assigning members of the panel to the boards; (3) recommending new members of the panel to the Commission; (4) preparing and maintaining hearing calendars of all cases assigned to the boards; (5) fixing or approving the time and place for hearings and prehearing conferences in cases assigned to the boards; (6) reporting to the Commission on activities of the boards; (7) presenting to the Commission recommendations relating to the conduct of hearings, hearing procedures, and policies for the guidance of the boards; (8) acting as spokesman for the panel in relations with the Commission and the Director of Regulation; (9) transmitting to, and interpreting for the panel, Commission policies and procedures affecting the conduct of the boards' activities; (10) maintaining liaison with the Director of Regulation on matters of policy, procedure and rules and regulations within his authority; and (11) performing such other duties as may be assigned by the Commission. The Vice Chairman will act for the Chairman of the panel in the Chairman's absence and perform other duties as requested by the Chairman. The panel will also have an Executive Secretary.

The establishment of a permanent Chairman of the Atomic Safety and Licensing Board Panel to perform such functions entails certain amendments to Parts 1 and 2 of the Commission's regulations. Since the amendments relate solely to rules of agency organization and rules of practice and procedure, public notice and procedures thereon are not required.

Accordingly, pursuant to the Atomic Energy Act of 1954, as amended, and the Administrative Procedure Act of 1946, as amended, the following amendments of Title 10, Chapter I, Code of Federal Regulations, Parts 1 and 2 are published as a document subject to codification, to be effective 30 days after publication in the Federal Register.

33 FR 6707
Published 5/2/68
Effective 5/2/68

Miscellaneous Amendments

Notice is hereby given of the amendment of 10 CFR Part 2 of the Atomic Energy Commission's regulations.

The amendments of §§ 2.701(a), 2.708 (f), and 2.802 of 10 CFR Part 2 pertain to the filing of documents relating to adjudications and petitions for rule making.

The amendment of § 2.701(a) provides that documents shall be filed with the Commission in adjudications subject to Part 2 either (1) by delivery to the Public Document Room at 1717 H Street NW., Washington, D.C., or (2) by mail or telegram addressed to the Secretary, U.S. Atomic Energy Commission, Washington, D.C. 20545. Attention: Chief, Public Proceedings Branch. The present provision in § 2.701(a) for filing of such documents with the Office of the Secretary at Commission Headquarters, Germantown, Md.; is deleted by the amendment.

Paragraph (f) of § 2.708 is amended to provide that documents filed thereunder with the Secretary should be directed to the attention of the Chief, Public Proceedings Branch.

Section 2.802 is amended to provide that petitions for rule making should be addressed to the Secretary, attention of the Chief, Public Proceedings Branch.

These amendments are intended to facilitate prompt receipt of such documents and petitions by the Public Proceedings Branch which is located in the Commission's offices in Washington, D.C.

Because these amendments relate solely to minor procedural matters, the Commission has found that general notice of proposed rule making and public procedure thereon are unnecessary and good cause exists to make the amendments effective upon publication in the FEDERAL REGISTER.

Accordingly, pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendments of 10 CFR Part 2 are published as a document subject to codification, to be effective upon publication in the FEDERAL REGISTER.

33 FR 8587
Published 6/12/68
Effective 7/12/68

MISCELLANEOUS AMENDMENTS TO CHAPTER

On November 22, 1967, the Atomic Energy Commission published in the FEDERAL REGISTER (32 F.R. 16050) proposed amendments of its rules of practice, 10 CFR Part 2, including amendments to Appendix A of that part, Statement of General Policy: Conduct of Proceedings for the Issuance of Construction Permits for Production and Utilization Facilities for Which a Hearing Is Required Under Section 189a of the Atomic Energy Act of 1954, As Amended (Statement of General Policy), and conforming amendments to 10 CFR Part 50, Licensing of Production and Utilization Facilities and 10 CFR Part 115, Procedures for Review of Certain Nuclear Reactors Exempted from Licensing Requirements. The proposed amendments were intended to expedite the Commission's facility licensing procedures in contested cases and clarify certain provisions in existing regulations.

The proposed amendments to Part 2 reflected in part the recommendations made by a three-member Regulatory Review Panel appointed by the Commission to study contested proceedings involving applications to construct and operate nuclear facilities. A contested proceeding is a proceeding in which there is a controversy between the AEC regulatory staff and the applicant concerning the issuance of the license or any of its terms and conditions, or in which a petition for leave to intervene in opposition to an application for a license has been granted or is pending before the Commission. The Panel's report was submitted on June 15, 1967.

All interested persons were invited to submit written comments and suggestions for consideration in connection with the proposed amendments within 60 days after publication of the notice of proposed rule making in the FEDERAL REGISTER. After careful consideration of the comments received, the Commission has adopted the amendments which follow. Except for minor and clarifying changes to paragraph (a) of section I, Preliminary Matters, and paragraph (e) of section II, Prehearing Conference, of Appendix A of Part 2, the amendments are the same as those set out in the notice of proposed rule making.

Section 2.714(a) of Part 2 now requires a petitioner for leave to intervene in a Commission proceeding to set forth, among other things, his contentions. The amendment of § 2.714(a) which follows requires those contentions to be reasonably specific. It also provides that petitions which set forth contentions relating only to matters outside the jurisdiction of the Commission will be denied. These amendments are designed merely to state more clearly the Commission's longstanding policy of excluding from consideration in licensing hearings matters which are outside the Commission's regulatory jurisdiction. As revised, § 2.714(a) also requires the petition to be filed within such time as may be specified in the notice of hearing, or as permitted by the presiding officer, and continues to provide that a petition which is not timely filed will be dismissed unless the petitioner shows good cause for failure to file it on time.

Section 2.721(b) of Part 2 has been amended to provide for the appointment of alternates for atomic safety and licensing boards who are qualified in the conduct of administrative proceedings. Section 2.721(b) presently provides for the appointment of technically qualified alternates for the boards.

Certain recommendations of the Regulatory Review Panel, and other perfecting or clarifying changes, are reflected in the amendments to the statement of general policy which follow. Those which may be of particular interest are: (1) a provision that pre-hearing conferences will usually be held in the Washington, D.C., area, but that due regard shall be had for the convenience and necessity of the parties or their representatives; (2) a provision recognizing that requests may be made for a separate hearing on the matter of site selection; (3) a provision indicating that it is desirable for the applicant's summary of the application to discuss the evolution of the proposed reactor design from the design of reactors which have previously been approved or built; (4) a provision encouraging the submission to the atomic safety and licensing board of the applicant's summary of the application, as well as the regulatory staff's safety analysis, at least two weeks prior to the date specified in the notice of hearing for the receipt of petitions for leave to intervene; (5) a provision that atomic safety and licensing boards, in testing the sufficiency of the information contained in the application and in the record, and the adequacy of the regulatory staff's review, to support the proposals of the Director of Regulation in an uncontested proceeding, should be mindful that the applicant, not the regulatory staff, is the proponent of the license; (6) a provision clarifying the point that in contested proceedings, an atomic safety and licensing board may obtain information from the Chairman or Vice Chairman of the Atomic Safety and Licensing Board Panel for the purpose of identifying relevant decisions or statements of Commission policy; and (7) a provision that two members of an atomic safety and licensing board constitute a quorum if one of those members is the member qualified in the conduct of administrative proceedings.

The amendments set out below are a further indication of the Commission's intention to adopt from time to time amendments of its regulations which experience in the operation of atomic safety and licensing boards might indicate as being necessary or desirable.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Parts 2, 50, and 115, are published as a document subject to codification, to be effective thirty (30) days after publication in the FEDERAL REGISTER.

34 FR 12254
Published 7/25/69
Effective 8/23/69

PART 2—RULES OF PRACTICE

Issuance of Licenses for Receipt, Storage, Packaging, and Transfer of Radioactive Wastes

On April 29, 1969, the Atomic Energy Commission published in the FEDERAL REGISTER (34 F.R. 7033) proposed amendments to certain sections of its rules of practice in 10 CFR Part 2. The proposed amendments would eliminate requirements for assignment of docket numbers, publication of notices of proposed action and issuance of licenses, and service of license applications and notices on State and local officials, with respect to applications for licenses to receive, package, or store waste byproduct, source, or special nuclear material for transfer to other licensees for ultimate disposal.

All interested persons were invited to submit written comments and suggestions for consideration in connection with the proposed amendments within 30 days after publication of the notice of proposed rule making in the FEDERAL REGISTER. After consideration of the comments received and other factors involved, the Commission has adopted the proposed amendments. The text of the amendments set out below is identical with the text of the proposed amendments published April 29, 1969.

The amendments will (1) accord applications for licenses involving only the receipt, storage, and packaging of waste materials, the same treatment accorded applications for other types of materials licenses, and (2) reduce unnecessary details in the Commission's materials licensing process. Applications for licenses authorizing ultimate disposal of waste materials by the licensee are not affected by the adoption of the amendments. Applications for such licenses will continue to be assigned docket numbers, and notice of proposed action, and issuance of any such licenses will continue to be published in the FEDERAL REGISTER and notification given to State and local officials.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments of Title 10, Chapter I, Code of Federal Regulations, Part 2, are published as a document subject to codification to be effective 30 days after publication in the FEDERAL REGISTER.

34 FR 13360
Published 8/19/69
Effective 9/18/69

Atomic Safety and Licensing Appeal Board

On January 18, 1969, the Atomic Energy Commission published in the FEDERAL REGISTER (34 F.R. 869) proposed amendments to its regulations in 10 CFR Parts 1, 2, 50, and 115 which would provide for the establishment of an Atomic Safety and Licensing Appeal Board to perform the review functions which would otherwise be performed by the Commission, and certain functions of the Commission on interlocutory matters, in certain licensing proceedings. All interested persons were invited to submit written comments and suggestions for consideration in connection with the proposed amendments within 60 days after publication of the notice of proposed rule making in the FEDERAL REGISTER. Upon consideration of the material submitted in response to the notice of proposed rule making and other factors involved, the Commission has adopted the amendments set out below, which are identical with the proposed amendments published January 18, 1969.

The Atomic Safety and Licensing Appeal Board established by the amendments which follow will perform the review functions which would otherwise be performed by the Commission, and certain functions of the Commission on interlocutory matters, in (a) such licensing proceedings as the Commission may specify, and (b) those proceedings on applications for licenses or authorizations for facilities in which the Commission has a direct financial interest. Proceedings on applications for licenses or authorizations for facilities in which the Commission has a direct financial interest are (1) proceedings on applications for authorizations under Part 115, "Procedures for Review of Certain Nuclear Reactors Exempted from Licensing Requirements", and (2) proceedings on applications for licenses or construction permits under Part 50, "Licensing of Production and Utilization Facilities", for facilities as to which the Commission has made an arrangement for financial assistance under section 31 of the Act, as amended, or has waived charges for use of special nuclear material or source material under section 53c.(4) or 63c. of the Act. If the proceeding is uncontested, the Appeal Board will perform the customary function of the Commission in deciding whether to review the initial decision on its own motion or allow the decision to become final. If the proceeding is a contested proceeding, the Appeal Board will consider the exceptions to the initial decision and make a decision thereon. In review of proceedings other than those in which the Commission has a direct financial interest, the Appeal Board is authorized, either in its discretion or on the direction of the Commission, to certify to the Commission for its determination, major or novel questions of policy, law or procedure.

The final decision of the Appeal Board in proceedings on applications for licenses or authorizations for facilities in which the Commission has a direct financial interest will constitute the final action of the Commission. In other proceedings, the Commission has reserved the right to review the Appeal Board's decision on its own motion, on the ground that the Appeal Board's decision (a) is, with respect to an important matter, in conflict with statute, regulation, case precedent, or established Commission policy and (b) (1) could significantly and adversely affect the public health and safety or the common defense and security, or (2) involves an important question or public policy.

The Commission intends to delegate its review function to the Appeal Board in a number of proceedings (both contested and uncontested) sufficient to give the Commission an adequate opportunity to evaluate the new review procedure. In any event, the Commission's review function in licensing proceedings on applications for licenses or authorizations for facilities in which the Commission has a direct financial interest will be delegated to the Appeal Board. The Commission expects thereby to be enabled to devote more of its time and energies to major matters of policy and planning.

The Appeal Board will be composed of the Chairman and Vice Chairman of the Atomic Safety and Licensing Board Panel and a third member of the panel who is technically qualifed, designated by the Commission for each proceeding.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments of Title 10, Chapter 1, Code of Federal Regulations, Parts 1, 2, 50, and 115 are published as a document subject to codification to be effective 30 days after publication in the FEDERAL REGISTER.

35 FR 5317
Published 3/31/70
Effective 4/30/70

On April 16, 1969, the Atomic Energy Commission published for comment in the FEDERAL REGISTER proposed amendments to its Rules of Practice, 10 CFR Part 2, and to its regulation, Licensing of Production and Utilization Facilities, 10 CFR Part 50, which would (1) define more precisely the significance of the issuance of a construction permit for a facility, (2) simplify and expedite the Commission's facility licensing process by eliminating the "provisional" operating license, and (3) clarify the Commission's position with respect to requirements for additional safety features after the issuance of a construction permit (34 F.R. 6540).

All interested persons were invited to submit written comments and suggestions for consideration in connection with the proposed amendments within 60 days after publication of the notice of proposed rule making in the FEDERAL REGISTER. Upon consideration of the comments received and other factors involved, the Commission has adopted the amendments set out below. The amendments are the same as the proposed amendments published April 16, 1969, except for (1) the elimination of the proposed amendments to § 50.35, other than those deleting the term "provisional" construction permit and a related note, and the proposed definition in § 50.2 of the "principal architectural and engineering criteria" of the proposed design of a facility; (2) the addition of conforming amendments to Part 170; and (3) the addition of minor corrective ammendments to §§ 50.35, 50.57 and proposed § 50.109.

The rapid changes in technology in the field of atomic energy result in the continual development of new or improved features designed to improve the safety of production and utilization facilities. Section 50.109 which follows defines the circumstances under which the Commission may require backfitting of facilities–that is, the addition or modification of structures, systems or components affecting the safety of the facility after the construction permit has been issued. It provides that the Commission may require backfitting if it finds that such action will provide substantial, additional protection which is required for the public health and safety or the common defense and security.

Section 50.109 is not, however, intended to affect the responsibility of applicants for, or holders of facility licenses to evaluate significant new information developed as a result of experience in the design, construction, testing and operation of facilities and the results of research and development programs bearing on the safety of facilities, and to recommend any additions to, or modification of facilities needed to protect the health and safety of the public.

In the past the Commission has issued "provisional" construction permits when an applicant has not supplied initially all of the technical information required to complete the application and support the issuance of a construction permit which approves all proposed design features. In practice, almost all construction permits have never been converted into "final" construction permits, but have merged directly into the operating license. The amendments of § 50.35 and conforming amendments to Parts 2 and 170 which follow eliminate the term "provisional" construction permit, thus conforming the terminology with Commission practice. The findings required for issuance of a construction permit would be the same as those which have been required for a "provisional" construction permit.

The proposed amendment to § 50.35 would have provided that the Commission, in issuing a construction permit would be approving the construction of the facility in accordance with the application, including the principal architectural and engineering criteria. "Principal architectural and engineering criteria" would have been defined, by amendment of § 50.2 to include (1) the principal design criteria, (2) the essential elements of the proposed design for certain structures, systems and components, (3) the design bases for protection against natural phenomena, and (4) the essential elements of the applicant's quality assurance program. On further consideration, it appears that the "essential elements of the proposed design" of the structures, systems and components of water-cooled nuclear power units referred to in the proposed rule required further definition involving additional study. Accordingly, the proposed amendments of § 50.35 other than those eliminating the term "provisional" construction permit and a related note and the proposed definition of "principal architectural and engineering criteria" in § 50.2 have not been adopted at this time.

By amendments to § 50.57, the "provisional" operating license, which is issued for an 18-month period, is eliminated. Temporary limitations on operation considered necessary for public health and safety will be incorporated in the full-term operating license as conditions. The elimination of the provisional operating license does not preclude the Commission from imposing all the limitations in the full-term operating license which may have been required in the provisional operating license. The findings required for issuance of an operating license are largely the same as those which have been required for a provisional operating license. The elimination of the provisional operating license removes one step in AEC's facility licensing process and is expected to reduce the time consumed in the facility licensing process without reducing the degree of protection of the public health and safety provided. Provisional operating licenses already issued will continue in effect in accordance with their terms. Conforming amendments with respect to the operating license have also been made to Parts 2 and 170.

Pursuant to the Atomic Energy Act of 1954 as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter 1, Code of Federal Regulations, Parts 2, 50 and 170, are published as a document subject to codification to be effective 30 days after publication in the FEDERAL REGISTER.

35 FR 11459
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[10 CFR Parts 2, 4, 7, 10, 20, 30, 31, 32, 33, 34, 35, 36, 40, 50, 55, 70, 71, 80, 81, 110, 115, 140, 170]

MISCELLANEOUS AMENDMENTS TO CHAPTER

The Atomic Energy Commission has adopted the amendments set forth below to the citations of authority in its regulations in 10 CFR Chapter I.

In addition, other amendments of a corrective editorial nature, such as corrections to statutory references, have been adopted.

Since the amendments are of a corrective editorial nature and no substantive changes in the regulations are effected, good cause exists for omitting notice of proposed rule making and public procedure thereon as unnecessary, and for making the amendments effective without the customary 30-day notice.

Accordingly, pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments of Chapter I, Title 10 of the Code of Federal Regulations are published as a document subject to codification to be effective upon publication in the FEDERAL REGISTER.

35 FR 19500
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Subpoenas; Production of Inspection Reports and Internal Working Papers

In its memorandum opinion of August 26, 1970, In the Matter of Northern States Power Co. (Monticello Nuclear Generating Plant, Unit 1), Docket No. 50-263, the Atomic Energy Commission directed the staff to give consideration to the institution of rule making proceedings for the purpose of making clarifying amendments to AEC regulations pertaining to the resolution of questions of privilege arising in AEC adjudicatory proceedings. The Commission has now adopted the amendments to its rules of practice in 10 CFR Part 2 which follow, clarifying its policy and revising its procedures with respect to the subpoena of AEC personnel and the production of Commission inspection reports and internal working papers in Commission adjudicatory proceedings.

An amendment to § 2.720, Subpoenas, dealing with the appearance of AEC personnel to give oral testimony, provides that AEC staff witnesses designated by the General Manager or the Director of Regulation, as appropriate, or their designees, will be made available for oral examination at the hearing or on deposition regarding any matter, not priveleged, which is relevant to the issues in the proceeding. The attendance and testimony of the Commissioners and named AEC personnel at a hearing or on deposition may not be required by the presiding officer, by subpoena or otherwise: *Provided*, That the presiding officer may, upon a showing of exceptional circumstances, such as a case in which a particular named AEC employee has direct personal knowledge of a material fact not known to the witnesses made available by the General Manager or the Director of Regulation, certify directly to the Commission for determination, prior to any ruling thereon, the matter of whether the attendance and testimony of named AEC personnel should be required. The provision for certification has been inserted to take care of exceptional cases which may not be foreseen. Since competent witnesses will be made available by the General Manager or the Director of Regulation, it is expected that such exceptional circumstances will rarely, if ever, occur.

In addition, written interrogatories may be submitted to and served on the Secretary of the Commission. They will be answered and signed by AEC personnel with knowledge of the facts designated by the General Manager or the Director of Regulation, as appropriate. The answers will be served by the Secretary of the Commission upon parties to the proceeding.

In view of the increasing number of adjudicatory proceedings, and the demands on the time and energies of AEC policymaking, supervisory and staff personnel, the Commission considers it desirable to provide a procedure and criteria for determining the appropriateness of attendance and testimony of such persons in AEC adjudicatory proceedings. The procedure and criteria established seek to accommodate the public interest in having participation by appropriate AEC personnel in resolving matters in issue in an adjudicatory proceeding with a parallel public interest in maintaining the efficient and expeditious conduct of this and other agency functions.

Section 2.720 has also been amended to provide that an application for the production of records or documents in the custody of the Commissioners and AEC employees will be processed under a new section dealing with production of AEC records and documents, § 2.744. An application for the production of records or documents in the custody of AEC personnel other than full-time AEC employees, such as advisors and consultants, will be immediately certified by the presiding officer to the Commission for determination.

The production of AEC records and documents is covered in new § 2.744. This section specifies that AEC will as a matter of policy produce, on the application of a party to an adjudicatory proceeding, and a showing of need and relevance, Commission inspection reports and other records and documents, the basic purpose of which is to record matters of fact relating to license applications or licensed activities, if the facts contained in those reports and documents are not otherwise available. Certain privileged matter would be deleted from those reports, records and documents, i.e., (1) opinions, evaluations, analyses, deliberations, recommendations, or advice; (2) information given in confidence and names of individuals, other than AEC personnel, providing such confidential information; (3) references to records and documents which may be withheld from public disclosure; (4) proprietary information; and (5) other privileged information, including classified information.

Internal working papers are defined to include (1) the following documents containing opinions, analyses, evaluations, deliberations, advice, or recommendations: (i) Interagency or intraagency reports; (ii) memoranda; (iii) letters; (iv) correspondence; (v) draft papers; (vi) minutes of meetings; and (vii) staff papers; and (2) internal instructions prepared for the guidance of AEC personnel containing instructions and guidelines for the conduct of inspections of licensed activities and instructions and guidelines for the evaluation of information related to license applications and licensed activities. Internal working papers and records and documents of the type specified in § 9.5 of Part 9 are treated as privileged and exempt from disclosure. If a party wishes to obtain such internal working papers, records, and documents, he must address an application to the presiding officer in writing setting forth his need for the records and documents and their relevancy to the issues in the proceeding. The requested internal working papers, records and documents, will be produced for the in camera inspection of the presiding officer exclusively and only to the extent necessary to determine (1) need and relevancy, (2) whether they are in fact internal working papers or other exempt records or documents, and (3) whether their production, if exempt, would nevertheless not be contrary to the public interest and would not adversely affect the rights of any person.

Upon a determination by the presiding officer that the party making the request has demonstrated need and relevancy and that the production of any privileged papers, records, and documents would not be contrary to the public interest and would not adversely affect the rights of any person, the General Manager or the Director of Regulation, as appropriate, will either authorize production of such records and documents or state any objections to production. If the General Manager or the Director of Regulation, as appropriate, objects to production of such papers, records, and documents, the matter will be certified to the Commission or the Atomic Safety and Licensing Appeal Board, as appropriate, for determination.

Conforming and clarifying amendments have also been made to §§ 2.740, 2.741, and 2.780.

It is expected that the new regulation will permit the maximum amount of production of AEC records and documents for use by parties to an adjudicatory proceeding consistent with the necessary protection of certain rights of privacy and agency operations with respect to information in AEC records and documents. The approach adopted is consistent with sound Governmental practice and the principles reflected in the Freedom of Information Act.

In the interest of orderly and expeditious conduct of its licensing proceedings, the Commission would emphasize the desirability in this area of discovery, as in others permitted by the rules of practice, of completing necessary discovery at the prehearing stage of the proceeding.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 301, 552, and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 2, are published as a document subject to codification, to be effective upon publication in the FEDERAL REGISTER.

35 FR 19655
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Miscellaneous Amendments

The Atomic Energy Commission has adopted several amendments to its Rules of Practice, 10 CFR Part 2, and its regulation, Licensing of Production and Utilization Facilities, 10 CFR Part 50, to reflect the enactment of Public Law 91-560 on December 19, 1970. That legislation amended the Atomic Energy Act of 1954, as amended, by, among other things, eliminating the requirement that the Commission make "a finding in writing that any type of utilization or production facility has been sufficiently developed to be of practical value for industrial or commercial purposes" before the Commission may issue commercial licenses under section 103 of the Act for such facilities. Under Public Law 91-560, utilization or production facilities for commercial or industrial purposes must be licensed under section 103. Excepted from this requirement are such facilities the construction or operation of which has previously been licensed under section 104b of the Act, such facilities constructed and operated under the Cooperative Power Reactor Demonstration Program unless section 103 licensing is specifically required by applicable law, and such facilities for which section 104b licensing is specifically authorized by law.

The legislation also revises the provisions of section 105c of the Act pertaining to antitrust review of facility license applications, allows different qualifications for the membership of the atomic safety and licensing boards authorized by section 191 of the Act, and amends section 182c of the Act to provide for publication of an application for a section 103 license for a facility for the generation of commercial power in such trade or news publications as the Commission deems appropriate to give reasonable notice to municipalities, private utilities, public bodies and cooperatives which might have a potential interest in the facility.

Subsection 105c(3) of the Act as amended by Public Law 91-560 applies to holders of construction permits issued under section 104b before amendment. It permits any person who intervened or sought by timely written notice to the Commission to intervene in the construction permit proceeding for the facility to obtain a determination of antitrust considerations or to advance a jurisdictional basis for such determination to obtain an antitrust review of the operating license application by written request made within 25 days after the date of publication in the FEDERAL REGISTER of notice of filing of the application for an operating license or December 19, 1970, whichever is later. The Commission's regulations at present do not require the filing of a separate application as such for an operating license when the initial application is for a "license to construct and operate" a facility. As was contemplated when the legislation was pending, the amendments of Part 50 which follow will require a separate application for an operating license to be filed in conjunction with the final safety analysis report (§§ 50.30, 50.55(d)).

In pending cases in which the final safety analysis report has been filed and to which section 105c(3) of the Act is applicable, the Commission is publishing a notice of receipt of application for the operating license in the FEDERAL REGISTER, with the appropriate notice to intervenors and persons who sought intervention at the construction permit stage. These pending cases are: Vermont Yankee Nuclear Power Corporation, Docket No. 50-271; Boston Edison Company, Docket No. 50-293; Duke Power Company, Dockets Nos. 50-269, 50-270, 50-287; Philadelphia Electric Company, Dockets Nos. 50-277, 50-278; and Maine Yankee Atomic Power Company, Docket No. 50-309.

Holders of construction permits covered by subsection 105c(3) who have not yet filed a final safety analysis report should file the necessary application pursuant to amended § 50.30.

Pursuant to subsection 105c(8), provision has been made for the inclusion of a condition in construction permits issued under section 103 for which the application was pending on December 19, 1970. The condition will also be included in those operating licenses to be issued for those reactors described in subsection 105c(3) where intervention on antitrust grounds had been sought at the construction permit hearing. This condition is intended to assure that findings and orders of the Commission with respect to antitrust matters under section 105c of the Act made subsequent to the issuance of the permit or license will be given full force and effect. The condition will permit the issuance of permits and licenses in pending cases without undue delay while preserving the Commission's authority to impose appropriate antitrust conditions if, after such further proceedings as may be conducted as a result of the Attorney General's recommendation or the request of any party who properly raises an antitrust issue, the Commission determines such conditions to be appropriate. The condition will provide that the license shall be subject to an antitrust review by the Attorney General pursuant to section 105c of the Atomic Energy Act of 1954, as amended; that the licensee shall furnish to the Commission such information as the Attorney General determines to be appropriate for the conduct of the review and the rendering of his advice with respect to the license; that the Commission may hold a hearing on antitrust matters on the recommendation of the Attorney General or at the request of a party to the proceeding; and that the licensee shall comply with any order or license condition subsequently made by the Commission pursuant to section 105c of the Atomic Energy Act of 1954, as amended, with respect to the activities licensed therein.

Amendments to § 2.101 provide that the notice published in the FEDERAL REGISTER of receipt of the application for a facility license under section 103 of the Act, except for applications for operating licenses for facilities which were subject to antitrust review at the construction permit stage (unless the Commission deems such review advisable on the ground that significant changes in the licensee's activities or proposed activities have occurred subsequent to the issuance of the construction permit), will also state that persons who wish to have their views on the antitrust aspects of the application presented to the Attorney General for consideration shall submit such views to the Commission within sixty (60) days after publication of the notice. The notice published in the FEDERAL REGISTER of receipt of the application for a facility operating license under section 104b of the Act will, when appropriate, also state that any person who intervened or sought by timely written notice to the Commission to intervene in the construction permit proceeding for the facility to obtain a determination of antitrust considerations or to advance a jurisdictional basis for such determination may, within 25 days after the date of publication, submit a written petition for leave to intervene and a request for a hearing on the antitrust aspects of the application.

Amendments to § 2.102 of Part 2 provide that the Director of Regulation will refer and transmit a copy of each application for a construction permit or an operating license for a utilization or production facility under section 103 of the Act, and each request, in a proceeding for an operating license for a utilization or production facility under section 104b of the Act; by any person who intervened or sought by timely written notice to the Commission to intervene in the construction permit proceeding to obtain a determination of antitrust considerations or to advance a jurisdictional basis for such determination, for an antitrust review under section 105c of the application for an operating license, to the Attorney General as required by section 105c of the Act. Subsection 105c(1) provides that the Attorney General will, within a reasonable time but in no event to exceed 180 days after receipt, render such advice to the Commission as he determines to be appropriate in regard to the finding to be made by the Commission as to whether the activities under the license would create or maintain a situation inconsistent with the antitrust laws specified in section 105a of the Act. The requirements do not apply to an application for an operating license for a production or utilization facility under section 103 of the Act, for which the construction permit was also issued under section 103, unless the Commission determines such review is advisable on the ground that significant changes in the licensee's activities or proposed activities have occurred subsequent to the previous review by the Attorney General and the Commission under section 105c of the Act in connection with the construction permit.

The amendments to § 2.102 also provide that the Director of Regulation will publish the Attorney General's advice in the FEDERAL REGISTER promptly upon receipt, and will make such advice a part of the record in any proceeding on antitrust matters conducted in accordance with subsection 105c(5) and section 189a of the Act. The Director of Regulation will also publish in the FEDERAL REGISTER a notice that the Attorney General has not rendered any such advice. The notice published in the FEDERAL REGISTER will also include a notice of hearing, if appropriate, or will state that any person whose interest may be affected by the proceeding may file a petition for leave to intervene and request a hearing on the antitrust aspects of the application. The notice will state that petitions for leave to intervene shall be filed within 15 days after publication of the notice.

A new § 2.104(c) has been added to Part 2 to provide that, in the case of an application for a construction permit or an operating license for a facility, on which a hearing is required by the Act or AEC regulations or in which the Commission finds that a hearing is required in the public interest for the consideration of the antitrust aspects of the application, the notice of hearing will, unless the Commission determines otherwise, state (1) a time of the hearing, which will be as soon as practicable after the receipt of the Attorney General's advice and compliance with section 189a of the Act and other provisions of Part 2;[1] (2) that the presiding officer will consider the issue of whether or not the activities under the proposed license would create or maintain a situation inconsistent with the antitrust laws as specified in section 105a of the Act; and (3) that matters of radiological health and safety and common defense and security, and matters raised under the National Environmental Policy Act of 1969, will be considered at another hearing for which a notice will be published pursuant to § 2.104 (a) and (b).

Changes have been made in §§ 2.721 and 2.787 to provide for three-member Atomic Safety and Licensing Boards and a three-member Atomic Safety and Licensing Appeal Board comprised of one member qualified in the conduct of administrative proceedings and two members who shall have such technical or other qualifications as the Commission deems appropriate to the issues to be decided, as permitted by the amendments to section 191 of the Act.

Amendments have been made to §§ 2.105, 2.714 and Appendix A of Part 2 to conform those provisions to the above-described changes in other sections of Part 2.

Sections 50.21, 50.22, and 50.41 of Part 50 have been amended to reflect the new definitions of section 103 and section 104 licenses in the Act. Section 50.24 has been deleted, since the substance thereof is now covered, pursuant to Public Law 91-560, in other sections.

Section 50.33 has been amended to reflect the amended provisions of section 182 of the Act (as has § 50.43). Under § 50.33, an applicant for a license for a facility for the generation of commercial power is required to identify the appropriate regulatory agencies having jurisdiction over the rates and services of the facility, and the trade and news publications in the area where the activity will be conducted which are appropriate to give notice to municipalities, private utilities, public bodies and cooperatives which might have a potential interest in the facility. It is expected that the information will be supplied after consultation with appropriate agencies.

Section 50.33, as amended, also requires the submission, with an application for a section 103 license (and a section 104 operating license as to which a person who intervened or sought by timely written notice to the Commission to intervene in the construction permit proceeding for the facility to obtain a determination of antitrust considerations or to advance a jurisdictional basis for such determination has requested an antitrust review under section 105 of the Act within 25 days after the date of publication in the FEDERAL REGISTER of notice of filing of the application for an operating license or Dec. 19, 1970, whichever is later) such information as the Attorney General determines to be appropriate for his antitrust review. It is anticipated that for pending applications, the information submitted to the Commission to establish financial qualifications under § 50.33(f) will form an adequate basis on which to start antitrust review. It is believed that experience with these cases will enable the Department of Justice to identify with more specificity what information should be required of applicants in future cases.

Section 50.42, which prescribes standards for the issuance of section 103 licenses, has been amended to provide that in any hearing on the antitrust aspects of the application, the Commission, if it finds that the proposed license would create or maintain a situation inconsistent with the antitrust laws as specified in subsection 105a of the Act, will consider, in determining whether a license should be issued or continued, such other factors as the Commission deems necessary to protect the public interest, including the need for power in the affected area.

A new § 50.55b has been added to Part 50, providing that the Commission may incorporate a condition in construction permits for section 103 facilities for which the application was pending on December 19, 1970, and operating licenses for section 104 facilities, as to which a person who intervened or sought by timely written notice to the Commission to intervene in the construction permit proceeding for the facility to obtain a determination of antitrust considerations or to advance a jurisdictional basis for such determination within 25 days after the date of publication in the FEDERAL REGISTER of notice of filing of the application for an operating license or December 19, 1970, whichever is later. The condition will provide that the license shall be subject to an antitrust review by the Attorney General pursuant to section 105c of the Atomic Energy Act of 1954, as amended; that the licensee shall furnish such information to the Commission as the Attorney General determines to be appropriate for the conduct of the review and the rendering of his advice with respect to the license; that the Commission may hold a hearing on antitrust matters on the recommendation of the Attorney General or at the request of a person whose interest may be affected by the proceeding and that on the basis of its findings made after such hearing the Commission will continue, rescind or amend the license to include such conditions as the Commission deems appropriate; and that the licensee shall comply with any order or license condition made by the Commission pursuant to section 105c of the Atomic Energy Act of 1954, as amended, with respect to the licensed activities.

Section 50.80 of Part 50, which deals with transfer of licenses, has been amended to require that applicants for transfer of a license, if the license will be issued under section 103, shall furnish such information to the Commission as the Attorney General determines to be appropriate for his antitrust review.

Since the amendments which follow relate to matters of procedure and practice, or merely conform the Commission's regulations to new statutory provisions, the Commission has found that general notice of proposed rule making and public procedure thereon are unnecessary, and that good cause exists for making the amendments effective upon publication in the FEDERAL REGISTER.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter 1, Code of Federal Regulations, Parts 2 and 50, are published as a document subject to codification to be effective upon publication in the FEDERAL REGISTER. The Commission invites all interested persons who desire to submit written comments or suggestions in connection with the amendments to send them to the Secretary of the Commission, U.S. Atomic Energy Commission,

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[1] As permitted by subsection 105c(8) of the Act, with respect to proceedings in which an application for a construction permit was filed prior to Dec. 19, 1970, and proceedings in which a written request for antitrust review of an application for an operating license to be issued under section 104b has been made by a person who intervened or sought by timely written notice to the Commission to intervene in the construction permit proceeding for the facility to obtain a determination of antitrust considerations or to advance a jurisdictional basis for such determination within 25 days after the date of publication in the FEDERAL REGISTER of notice of filing of the application for an operating license or Dec. 19, 1970, whichever is later, the Commission may issue a construction permit or operating license in advance of consideration of, and findings with respect to, the antitrust aspects of the applications: *Provided*, That the permit or license so issued contains the condition described in new § 50.55b.

Washington, D.C. 20545, Attention: Chief, Public Proceedings Branch, within 60 days after publication of this notice in the FEDERAL REGISTER. Copies of comments received may be examined at the Commission's Public Document Room at 1717 H Street NW., Washington, DC.

36 FR 13270
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Time for Filing Petition for Leave to Intervene on Antitrust Aspects of Facility License Application

The Atomic Energy Commission has adopted an amendment of § 2.102(d)(3) of its Rules of Practice, 10 CFR Part 2, pertaining to the time within which a petition for leave to intervene and request for a hearing on the antitrust aspect of a facility license application must be filed. Presently, the notice published by the Commission in the FEDERAL REGISTER of the Attorney General's advice on the antitrust aspects of a facility license application states that petitions for leave to intervene and request for a hearing shall be filed within 15 days after publication of the notice. The amendment of § 2.102(d)(3) which follows provides that the notice will state that such petitions and requests shall be filed within 30 days after publication of the notice. A conforming amendment has also been made to Appendix A of Part 2, a statement of general policy pertaining to the conduct of proceedings for the issuance of licenses for production and utilization facilities for which a hearing is required under section 189a of the Atomic Energy Act of 1954, as amended.

Since the amendments relate solely to the Commission's Rules of Practice, notice of proposed rule making and public procedures thereon are not required.

Accordingly, pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments of Title 10, Chapter I, Code of Federal Regulations, Part 2, are published as a document subject to codification, to be effective upon publication in the FEDERAL REGISTER (7-17-71).

36 FR 16894
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CIVIL PENALTIES

On December 17, 1970, the Atomic Energy Commission published in the FEDERAL REGISTER (35 F.R. 19122) proposed amendments to 10 CFR Part 2, "Rules of Practice", regarding civil penalties.

The proposed amendments set out the procedures which the Commission proposed to follow in imposing civil penalties authorized under section 234 of the Atomic Energy Act of 1954, as amended (the Act). Conforming amendments to 10 CFR Parts 20, 30, 40, 50, 55, 70, 71, 73, and 150 were also proposed.

Interested persons were invited to submit written comments and suggestions for consideration in connection with the proposed amendments within 60 days after publication of the notice of proposed rule making in the FEDERAL REGISTER. After consideration of the comments received and other factors involved, the Commission has adopted the proposed amendments with certain modifications.

Significant differences from the amendments published for comment are:

(1) Section 2.700, which describes the scope of Subpart G, governing procedure in Commission adjudications, has been amended to cover specifically hearings held on civil penalties.

(2) The provision in proposed § 2.205 for requesting a hearing in connection with the assessment of a civil penalty has been revised to make clear that a request for a hearing need not be made until after an answer to a notice of violation has been filed and an order imposing a civil penalty entered by the Director of Regulation.

(3) The provision in proposed § 2.205 for reference of unpaid civil penalty orders to the Attorney General for collection has been clarified to cover specifically situations in which no answer is filed or an answer is filed but no hearing is requested, as well as situations in which the order is issued after a hearing.

(4) Section 2.203, which requires approval of the presiding officer of a stipulation for settlement in other enforcement proceedings (such as modification, suspension or revocation of a license) has been amended to include also compromise of civil penalties. Since a monetary penalty would be assessed as a deterrent to actions which affect such important matters as the public health and safety and the common defense and security, it appears that, once the matter has been set for hearing, the compromise of a civil penalty, like the settlement of a matter involving a situation such as license suspension or revocation imposed for the same reasons, should not be effected without the approval of the presiding officer. The provision in proposed § 2.205 to the effect that the Director of Regulation may compromise any civil penalty has been revised to reflect the amendment of § 2.203.

Editorial and organization changes have also been made.

Several comments noted the absence of criteria to be used by the Commission in defining the types of cases in which civil penalties will be used and the size of civil penalties likely to be imposed. Although subject to modification, as experience is gained, the Commission's plans for utilization of civil penalties are described below.

Civil penalties, as a method of enforcement, are believed to be appropriate in cases where the illegal acts do not involve an immediate serious threat to public health and safety or the common defense and security (such as the diversion of nuclear materials), but the circumstances of the case indicate that an enforcement measure more severe than a notice of violation is appropriate. Civil penalties, where appropriate, will provide suitable remedial action without the undesirable side effects of suspension or revocation, such as depriving a licensee or his employees of their means of livelihood or the public of an essential service.

Cases involving an immediate serious threat to public health and safety or the common defense and security (such as the diversion of nuclear materials) will continue to be handled by immediate steps as necessary to remove the threat, and by enforcement action such as license suspension or revocation, cease and desist order, or other appropriate action.

Civil penalties and other enforcement methods are, however, not necessarily mutually exclusive and may in appropriate cases be cumulative. For example, rather than a lengthy suspension, a briefer suspension coupled with a civil penalty might be best adapted to the enforcement situation.

The Commission believes that the following cases are typical of those that would be appropriate for imposition of a civil penalty, when the violations represent a threat to public health and safety or the common defense and security (such as the diversion of nuclear materials), but the threat is not of an immediate nature:

(1) Those in which a licensee is found to have repeated violations of license requirements.

(2) Those in which a licensee has willfully violated the provisions of the Commission's rules or regulations or conditions of the license.

(3) Those cases in which a licensee fails to take timely corrective action on matters which may affect public health and safety or the common defense and security (such as the diversion of nuclear materials), and which have previously been brought to the attention of the licensee.

(4) Certain cases in which a person has violated the various requirements for a license in the Act and in the Commission's regulations.

In addition, violations which do not represent a threat to public health and safety or the common defense and security (such as the diversion of nuclear materials) will be subject to a civil penalty if it is determined that the violations are willful.

In determining the amount of a suitable penalty, the Commission will consider all relevant factors including, among others, the nature and number of the violations (i.e., the significance from the standpoint of health and safety of the public or of the common defense and security such as safeguarding of special nuclear material), the steps taken by the person to correct the violations, the licensee's history of previous violations and his demonstrated good faith in correcting them promptly, and the appropriateness of the penalty to the size of the licensee's business conducted under license. Where a person is found to have multiple violations, the amount of the penalty would be multiplied by the number of violations. Furthermore, section 234 of the Act provides that if any violation is a continuing one, each day of violation shall constitute a separate violation for the purpose of computing the applicable civil penalty. In a case where, despite the exercise of reasonable diligence, a licensee was not aware of the violation until brought to its attention by the Commission, the computation of the period of violation would normally begin at that time or after the time allowed the licensee for corrective action. On the other hand, if the evidence showed that a licensee had knowingly permitted violations to continue, the computation of the period of violation might begin at the time the licensee permitted the violations to continue.

In summary, a penalty of up to $5,000 may be imposed for each violation and for each day that the violation exists, up to a maximum total penalty of $25,000 during a 30-day period. Generally, however, the notice of violation will specify the total penalty being assessed, which will include consideration of the number of violations and the number of days the violations have existed. The notice of violation could also impose a daily penalty which would accrue, if the violations are not corrected as of a prescribed date.

The Commission plans to assess civil penalties in amounts ranging up to a maximum of $5,000 per violation. Such factors, among others, as the extent of the threat to public health and safety or the common defense and security resulting from the violation, the willfulness of the violation and the number of similar violations by the person charged will be considered in fixing the amount of the civil penalty. As experience in the use of civil penalties for enforcement purposes is gained, the Commission may develop and publish additional criteria for the determination of the amounts of civil penalties for specific types of violations.

Several of the comments expressed concern about such matters as the failure of the proposed amendments to provide specifically for informal conferences with the regulatory staff or the Director of Regulation with respect to the subject matter of the notice of violation or the amount of the proposed penalty either before or after the notice of violation is sent; the use of the term "notice of violation" rather than "notice of alleged violation"; the fact that the Director of Regulation has been delegated authority by the Commission to institute the notice of violation and proposed penalty and also has been delegated authority to consider the answer and revise the penalty thereafter; and the failure to provide specifically for alternative actions such as cease and desist orders.

Most of the above comments would apply equally to the other provisions of Subpart B of Part 2 dealing with other types of enforcement action. It has not proved necessary in the past to refer to "alleged violations" rather than "violations" or provide specifically in the regulation for such matters as informal conferences on the subject matter of the violation or the proposed enforcement action, which are, of course, available to persons charged with violation of AEC regulations. No persuasive reason has been presented for making such changes in Part 2 with respect to civil monetary penalties, which are less drastic than other available enforcement actions such as suspension or revocation of a license.

The Commission considers that the provisions of §§ 2.205 and of 2.203, which have been specifically made applicable to civil penalty proceedings, are sufficient to permit the informal disposition of proceedings for imposition of civil penalties.

The Commission does not view as unfair or otherwise inappropriate the fact that the Director of Regulation will have authority to institute the proceeding for the imposition of a civil penalty and will also have authority to consider the answer to the charges and thereafter revise, impose or mitigate the penalty, particularly in view of the opportunity provided for an administrative hearing before an officer other than the Director of Regulation and for a trial de novo in a civil action to collect a civil penalty under section 234c of the Act.

Under the Commission's organization, inspectors and first-line supervisory personnel would not be authorized to impose civil penalties. The pertinent delegations of authority from the Director of Regulation to the Directors of the Divisions of Compliance and Nuclear Materials Safeguards, and delegations from the Directors to their staffs will be available for inspection in the Commission's Public Document Room at 1717 H Street NW., Washington, D.C.

The Commission does not view a decision to institute proceedings for the imposition of a civil penalty as precluding the use of other kinds of enforcement action, if such other action later appears desirable. However, it is not deemed necessary to provide specifically for such alternatives.

The comments exhibited disparate views on the matter of whether the notice pertaining to the proposed imposition of civil penalties should be included in the notice of violation issued pursuant to § 2.201. Ordinarily, such notices will be combined wherever practicable. The amendments set forth below, however, do not require a combined notice. There may be occasions when the Commission will wish to issue a notice of proposed imposition of civil penalty if no answer, or an inadequate answer, is received to a notice of violation issued under § 2.201 (a). Conversely, if it is initially determined that the imposition of a civil penalty is appropriate in a particular case of violation, it would be appropriate to inform the person charged with violation of the intended enforcement action at the time the notice of violation is issued.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Parts 2, 20, 30, 40, 50, 55, 70, 71, 73, and 150, are published as a document subject to codification effective thirty (30) days after publication in the FEDERAL REGISTER.

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36 FR 18173
Published 9/10/71

Civil Penalties, Correction

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37 FR 6380
Published 3/29/72
Effective 3/29/72

Atomic Safety and Licensing Appeal Board

The Atomic Energy Commission's rules of practice, 10 CFR Part 2, provide for the establishment of an Atomic Safety and Licensing Appeal Board to perform the review function which would otherwise be performed by the Commission in certain licensing proceedings. Section 2.787 of 10 CFR Part 2 describes the composition of the Appeal Board as "the Chairman, Vice-Chairman, and a third member designated by the Commission for each proceeding, except that in proceedings involving antitrust considerations, it is composed of the Chairman and two members designated by the Commission possessing qualifications appropriate to the issues to be decided."

The Commission has amended § 2.787 of 10 CFR Part 2 to provide for the designation of alternate members of the Atomic Safety and Licensing Appeal Board. If a member of the Appeal Board, including the Chairman or Vice-Chairman, becomes unavailable, an alternate will be designated by the Commission to serve as a member of the Appeal Board.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendment to Title 10, Chapter 1, Code of Federal Regulations, Part 2, is published as a document subject to codification, to be effective upon publication in the FEDERAL REGISTER (3-29-72).

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Temporary Operating Licenses

The Atomic Energy Commission has adopted amendments to its rules of practice, 10 CFR Part 2, and its regulation, licensing of production and utilization facilities, 10 CFR Part 50, to reflect the enactment of Public Law 92-307 on June 2, 1972.

Public Law 92-307 added a new section 192 to the Atomic Energy Act of 1954, as amended, (the Act) providing for the use of expedited procedures, in proceedings in which a hearing is otherwise required before issuance of an operating license, in connection with the issuance of certain temporary operating licenses for nuclear power reactors whose electrical energy is needed to meet specified energy needs. The hearing on the temporary operating license is to be conducted with expedited procedures as the Commission may by rule, regulation, or order deem appropriate for a full disclosure of material facts on all substantial issues raised in connection with the proposed temporary operating license.

Under the Act, prior to the addition of new section 192, the Commission was afforded considerable flexibility to develop and apply hearing procedures suitable to the nature of its proceedings. Section 192 is in no way a limitation on the Commission's preexisting authority; rather, in keeping with the expedited procedures now mandated, it expands the procedural flexibility formerly provided. The new procedures set out below, in conformity with the intent and thrust of Public Law 92-307, are specifically directed to the potential emergency power needs of this year and next.

The temporary operating licenses authorized by new section 192 would not deprive the public of a full substantive review of the health and safety and environmental matters which may be contested. All substantive requirements of applicable law would have to be satisfied. The safety evaluation by the AEC's regulatory staff and the report of the Advisory Committee on Reactor Safeguards on the project would have to be available.

The temporary operating license is to be vacated if the Commission finds that the applicant is not prosecuting the application for the full-term license with due diligence. The issuance of a temporary license would not prejudice the position of any party who is participating in the contested hearing on the full-term license.

The legislation provides for the filing of affidavits either in support of or in opposition to a petition for a temporary operating license. The hearing on the petition is not necessarily to be a trial-type hearing. If the affidavits raise a substantial issue of material fact, which, in the judgment of the Commission, must be considered for the purposes of the findings required to support issuance of the temporary operating license, the hearing would provide an opportunity, under the expedited procedures referred to above, and to the extent considered necessary by the Commission, for interested parties to present evidence and ask questions pertinent to the substantial issue of material fact. This authority can be used in contested hearings and proceedings which are pending and in progress on the date of enactment of Public Law 92-307. If a temporary license is issued by the Commission, the final Commission action would be subject to judicial review under the Administrative Orders Review Act of 1950. The authority to issue temporary operating licenses pursuant to the legislation is limited to October 30, 1973.

The amendments to Parts 2 and 50 set out below are designed to conform Commission regulations and procedures to the new legislation.

A new § 50.57(d) has been added to reflect the Commission's authority, granted by Public Law 92-307, to issue temporary operating licenses for emergency purposes under expedited procedures. The new paragraph provides that where a hearing is required in a pending proceeding for a full-term license, a motion for a temporary operating license may be filed with the presiding officer and shall be accompanied by an affidavit or affidavits setting forth the facts upon which the applicant relies to justify issuance of a temporary operating license. Any party to the proceeding may file affidavits in support of, or in opposition to, the motion within specified time limits.

A temporary operating license may be issued upon findings that:

(i) The provisions of section 185 of the Act have been met with respect to the temporary operating license;

(ii) Operation of the facility during the period of the temporary operating license in accordance with its terms and conditions will provide adequate protection of the environment during the period of the temporary operating license; and

(iii) Operation of the facility in accordance with the terms and conditions of the temporary operating license is essential toward insuring that the power generating capacity of a utility system or power pool is at, or is restored to, the levels required to assure the adequacy and reliability of the power supply, taking into consideration factors which include, but need not be limited to, alternative available sources of supply, historical reserve requirements for the systems involved to function reliably, the possible endangerment to the public health and safety in the event of power shortages, and data from appropriate Federal and State governmental bodies which have official responsibility to assure an adequate and reliable power supply.

The presiding officer will hold a hearing on that motion and any supporting material after ten (10) days notice and publication once in the FEDERAL REGISTER. The hearing will be limited to oral argument deemed pertinent by the presiding officer to the above findings and, in the event any substantial issues of material fact are raised in the affidavits filed in connection with the proposed temporary operating license, as determined by the presiding officer, the presentation of evidence and asking of questions to the extent considered necessary by the presiding officer for the full disclosure of such facts or to facilitate the resolution of such issues. The hearing will be conducted in accordance with expedited procedures set out in a new Subpart F of Part 2. The presiding officer will make appropriate findings as specified above. If the findings are in the affirmative, an order will be issued authorizing issuance of a temporary operating license for the requested operation.

Any decision or other document authorizing the issuance of a temporary operating license will recite with specificity the reasons justifying the issuance. The temporary operating license will contain such terms and conditions as the Commission deems appropriate, including the requirement that the licensee not retire, dismantle, or perform any maintenance that could reasonably be delayed on any of its existing generating capacity on the ground of the availability of the capacity from the facility which is operating under the temporary license.

Any temporary operating license issued before the final detailed statement on the environmental impact has been completed will be further subject to the provisions of amended section D of Appendix D to Part 50. In that case, the issuance of the temporary operating license will also require either (1) a finding that the proposed licensing action will not have a significant adverse impact on the quality of the environment; or (2) consideration and balancing of specified environmental and public interest factors. In such a case, temporary operation beyond twenty percent (20%) of full power will not be authorized except upon specific prior approval of the Commissioners.

The availability of expedited procedures for a temporary operating license does not preclude an applicant from making a motion for a license for limited operation pursuant to the Commission's present regulations in Part 50 and, if the motion is opposed, the issuance of such a license after compliance with the provisions of Subpart G of Part 2. Moreover, atomic safety and licensing boards are expected to avoid unnecessary duplication in situations where an applicant, who has previously filed such a motion for limited operation, elects to file a new motion under the expedited procedures now provided.

As noted above, the expedited procedures for use in hearings on temporary operating licenses are outlined in a new Subpart F of Part 2.

The hearing required to be held on a motion for a temporary operating license is not necessarily a trial-type hearing. As the Report of the Joint Committee on Atomic Energy (H.R. Rept. No. 92-1027, S. Rept. No. 92-787) states, the requirement for a trial-type hearing was not considered appropriate to provide the procedural flexibility needed for the Commission to be responsive to emergency situations. The basic purpose of the hearing on the temporary operating license is to amplify, to the extent necessary, matters that have been put forward in the required affidavits and pleadings. If the required affidavits do not raise a substantial issue of material fact which, in the judgment of the presiding officer, must be considered for the purposes of the findings in subsection 192b of the Act, there would be no need for the presentation of evidence or the asking of questions.

In this connection, it may be noted that statutes providing for adjudications required to be determined on the record after opportunity for agency hearing—that is, a proceeding subject to sections 5, 7, and 8 of the Administrative Procedure Act (5 U.S.C. 554, 556, and 557)—have been construed as not requiring an evidentiary hearing when no issues of material fact are presented, or as affording the agency a degree of flexibility in determining the procedures appropriate to the issues presented, particularly when time is of the essence, Citizens for Allegan County v. FPC, 414 F. 2d 1125 (D.C. Cir., 1969); Persian Gulf Outward Freight Conf. v. Federal Maritime Commission, 375 F. 2d 335 (D.C. Cir., 1967); Marine Space Enclosures, Inc. v. Federal Maritime Commission, 420 F. 2d 577 (D.C. Cir., 1969). The Report of the Joint Committee on Atomic Energy on Public Law 92-307 (H.R. Rept. No. 92-1027, S. Rept. No. 92-787) shows (p. 9) that the Congress was aware of this judicial construction of the "hearing" requirements of regulatory statutes. As noted above, under the Act, prior to the addition of new section 192, the Commission was afforded considerable flexibility to develop and apply hearing procedures suitable to the nature of its proceedings.

Subpart F provides atomic safety and licensing boards with additional authority and flexibility to tailor the hearing procedures to the particular circumstances and to achieve the required and expected degree of expedition. In consonance with the legislative mandate that these procedures be "expedited procedures," the presiding officer is directed to establish a proceeding schedule with appropriate time limitations for each phase. While, in keeping with the expedited nature of the proceeding, no requests for interrogatories, depositions, or other discovery will be entertained, in the absence of extraordinary circumstances as determined by the presiding officer, the Commission intends to make publicly available on a liberal basis, documents in its files pertinent to issues stated for consideration in the notice of hearing. Furthermore, the Commission expects applicants for temporary operating licenses to do the same with respect to such documents in their files. Any failure on the part of applicants to make such documents available should be considered by the presiding officer in determining the adequacy of the basis for a decision.

Unless the presiding officer finds that the presentation of evidence is necessary either for full disclosure of material facts on a substantial issue raised in connection with the proposed temporary operating license or to facilitate the resolution of any such substantial issue, the hearing will be limited to oral argument. If any substantial issue of material fact raised in the affidavits is specified for consideration in the notice of hearing, the parties to the proceeding will be permitted to present evidence and ask questions pertinent to such issue to the extent considered necessary by the presiding officer. The hearing will not be used as an occasion for reopening matters which have already been considered in the proceeding nor issues which relate to the full-term license rather than the temporary license. In view of the statutory mandate for expedition, the presiding officer is expected to be particularly mindful of the need for preventing abuse of the hearing process. It is expected that the hearing will not be adjourned once begun, but will continue until concluded.

After the hearing on the temporary operating license, the presiding officer will promptly make the findings required by Public Law 92-307, and the Commission's regulations. Unless the Commission orders otherwise, the presiding officer on a motion for issuance of a temporary operating license would be the presiding officer designated for the hearing on the application for a full-term license. The presiding officer is expected to give appropriate priority to the temporary operating license proceeding in view of the nature of the proceeding.

The Commission is aware that the expedited procedures outlined here will impose a substantial burden on all of the parties to a proceeding. The need for a prompt decision when emergency situations arise warrants these procedures. These procedures will assure a fair hearing and a prompt decision if the parties will abide by them in good faith. An applicant filing a motion for a temporary operating license has a heavy responsibility to provide sufficient factual justification so that further requests for data will be unnecessary. This will require the disclosure of substantial underlying data relating to the duration of the authority and the level of operation sought, and it will not be sufficient for the applicant to present merely unsupported opinions.

The other parties also have a heavy burden. They must establish the substantial issues of material fact at an early date and develop specific contentions with reference to those issues. Equally important is the need to focus on the contested substantial issues of material fact in such a way that the need for evidentiary presentations or questions, if any, is apparent. The use of broad unsupported attacks or attempts to relitigate issues already foreclosed in the hearing on the full-term license will not be permitted.

A draft of the amendments set out below was placed in the Commission's Public Document Room on May 30, 1972. In addition, counsel for parties participating in pending proceedings on applications for operating licenses for nuclear power reactors were invited by the staff to attend a meeting on June 2, 1972, to discuss the amendments. Some of the comments received at that meeting are reflected in the amendments set out below.

In the formulation of the amendments set out below, the Commission has had the benefit of the analysis and recommendations contained in a petition for rule making filed on May 17, 1972, by the Environmental Defense Fund, Inc. The Commission has given careful consideration to that petition and is appreciative of the analysis and recommendations made therein.

Since the amendments which follow are intended to implement in the Commission's regulations new statutory provisions which recognize the need for, and direct expedition in temporary operating license proceedings, the Commission has found that general notice of proposed rule making and public procedure thereon are impracticable, and that good cause exists for making the amendments effective upon publication in the FEDERAL REGISTER.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter 1, Code of Federal Regulations, Parts 2 and 50, are published as a document subject to codification to be effective upon publication in the FEDERAL REGISTER.

The Commission invites all interested persons who desire to submit written comments or suggestions for consideration in connection with the amendments to send them to the Secretary of the Commission, U.S. Atomic Energy Commission, Washington, D.C. 20545, Attention: Chief, Public Proceedings Branch, within 30 days after publication of this notice in the FEDERAL REGISTER. Consideration will be given to such submission with the view to possible further amendments. Copies of comments received by the Commission may be examined at the Commission's Public Document Room, 1717 H Street NW., Washington, DC.

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RESTRUCTURING OF FACILITY LICENSE APPLICATION REVIEW AND HEARING PROCESSES

On May 9, 1972, the Atomic Energy Commission published in the FEDERAL REGISTER (37 F.R. 9331) proposed amendments to its regulations which would restructure its facility license application review and hearing processes. The proposed amendments to Part 2 related primarily to applications for licenses for production and utilization facilities. The proposed amendments to Appendix A of Part 2 related primarily to applications for licenses to construct or operate power and test reactors and fuel reprocessing plants. The proposed amendments to Appendix D of Part 50, which applies to such facility and materials licenses as are subject to requirements for environmental impact statements pursuant to the National Environmental Policy Act of 1969 (NEPA), would conform Appendix D, as necessary, to the proposed amendments to Part 2, and make other changes to that appendix.

The proposed amendments would implement concepts outlined in a public announcement issued by the Commission on November 19, 1971 ("AEC Considering Extensive Rule Changes to Reshape Regulatory Process"). In March of this year a draft version of the amendments was circulated widely to environmentalist groups and to representatives of the nuclear power industry and discussed at a Commission-sponsored conference.

Interested persons were invited to submit written comments and suggestions for consideration in connection with the proposed amendments within 30 days after publication of the notice of proposed rule making in the FEDERAL REGISTER. After careful consideration of the comments received and other factors involved, the Commission has adopted the proposed amendments with certain modifications, in the form set forth below.

There has developed a widely shared concern as to the ability of the Commission's licensing process, as presently structured, to cope with the demands being placed upon it. Thus, at a time when there is sharply increasing demand for more electrical power, and when nuclear facilities are being called upon to meet a constantly mounting share of the demand, there are increasing delays in completing the decisional process with respect to the construction and operation of those facilities. The Commission is concerned not only with its obligation to the segment of the public participating in licensing proceedings but also with its responsibility to the general public—a responsibility to arrive at sound decisions, whether favorable or unfavorable to any particular party, in a timely fashion. The Commission expressly recognizes the positive necessity for expediting the decisionmaking process and avoiding undue delays. It expects that its responsibilities under the Atomic Energy Act of 1954, as amended, the National Environmental Policy Act of 1969, and other applicable statutes, will be carried out in a manner consistent with this policy in the overall public interest.

The dimensions of the problem are reflected in the increasingly lengthy proceedings in facility licensing. In some cases, hearing times are beginning to be measured in years. Parenthetically, the time interval between the filing of an application and the granting of a construction permit or operating license for a nuclear power reactor has been increasing in recent years on the average of 20 percent annually. Additional responsibilities stemming from recent statutes and court decisions underscore the scope and potential seriousness of the problem.

The Commission, in considering the kinds of changes in its licensing program that can best serve the fulfillment of its broad responsibilities, has given equal attention to the past participation of industry, intervenors, and the staff in the process.

Significant differences from the amendments published for comment are:

1. Section 2.104 has been changed so that the provision for publication of a notice of hearing at least 30 days prior to the date set for hearing will apply only to applications for construction permits for power and test reactors and fuel reprocessing plants. In the case of an application for a construction permit for any other type of facility, or an operating license for any facility, the notice of opportunity for hearing pursuant to section 189 of the Atomic Energy Act gives 30 days' opportunity to file a petition for leave to intervene. If such a petition is received, and the Commission thereupon issues a notice of hearing, an additional 30 days before commencement of the hearing is not required. The section has also been amended to clarify that an additional 30-day notice is not required when the time and place of hearing are set by order of the presiding officer after the notice of hearing has been published.

2. Section 2.707, *Default*, has been amended to provide sanctions for failure to comply with the discovery provisions or with prehearing orders. In order to control the course of the proceeding, the presiding officer should have the necessary authority to impose appropriate sanctions on all parties who do not fulfill their responsibilities as participants.

3. Section 2.713 of Part 2, which presently authorizes suspension or barring from participation in a proceeding of attorneys who engage in dilatory tactics or disorderly or contemptuous conduct, has been amended to also specifically provide for suspension or barring of any person who the presiding officer finds

(a) Is not an attorney at law in good standing admitted to practice before any court of the United States, the District of Columbia, or the highest court of any State, territory, or possession of the United States;

(b) Has failed to conform to the standards of conduct required in the courts of the United States;

(c) Is lacking in character or professional integrity; or

(d) Displays toward the Commission or any of its presiding officers conduct which, if displayed toward any court of the United States, would be cause for censure, suspension, or disbarment.

Before any person is suspended or barred from participation as an attorney in a proceeding, charges will be preferred by the presiding officer and he will be afforded an opportunity to be heard thereon before another presiding officer.

4. A new § 2.740 has been added to Part 2 containing general provisions relating to discovery—scope of discovery, protective orders, and motions to compel discovery. The new section adapts Rules 26 and 37 of the Federal rules of Civil Procedure to Commission proceedings. Of particular interest are the provisions pertaining to discovery of trial preparation materials and supplements to discovered material.

5. Section 2.749, relating to summary disposition on the pleadings, has been revised to track more closely the Federal rules of Civil Procedure.

6. Section 2.758, pertaining to challenges of AEC regulations in adjudicatory proceedings, has been changed to clarify that such "challenges" can be made only on the ground that special circumstances in the particular proceeding are such that application of the regulation would not serve the purposes of the rule and justify a waiver or exception to the general rule. In this connection, § 2.802 has been amended to permit a petition for stay of a licensing proceeding pending action on the petition.

8. The provision for a summary statement of the application by the license applicant in Appendix A of Part 2 has been eliminated.

9. Section 9.5 of 10 CFR Part 9 has been amended to delete the exemption for material withheld from public disclosure to § 2.790. It is not the Commission's intent to permit a greater degree of withholding of documents from public disclosure under § 2.790 than would be permitted under the Freedom of Information Act.

10. Section 2.753, pertaining to stipulations, has been expanded to permit stipulations as to procedure as well as to facts or contents or authenticity of documents.

11. The provision in Appendix A of 10 CFR Part 2 to the effect that it is expected that ordinarily a board will render its initial decision within 45 days after receipt of proposed findings of fact and conclusions of law in a contested case and 15 days after such receipt in an uncontested case has been changed to indicate that the expected periods will be 35 days and 15 days, respectively. Other changes of a minor or clarifying nature have also been made.

The amendments set forth below may be generally classified in the following groups: Handling of applications for construction permits and operating licenses; discovery (including depositions, interrogatories, and production of documents); intervention and classes of participants; prehearing conferences, including encouraging stipulations and authentication of documents through prehearing conferences; consolidation of parties; limitation of issues in operating license hearings; improvements in the public hearing process, including limitations on time allotted for the conduct of the culminating hearing phase; advance written testimony; authority of presiding officers to regulate hearings; summary disposition on pleadings; consideration of Commission rules in quasi-adjudicatory proceedings; official notice; and recognition of the public interest in fair and reasonable settlements.

The amendments do not involve drastic changes in the administrative process or novel procedures. Several are interrelated, but few depend on the use of others. Almost all of them have been tried in one or more Federal agencies with positive results.

1. *Handling of applications for facility construction permits and operating licenses.* Under past practice, facility license applications, no matter how deficient, were accepted for docketing. In general, the deficiencies were cured after exchanges of questions from the regulatory staff and answers by the applicant. This time-consuming process created additional staff work and contributed to the overall length of the initial review. The process can be improved and expedited by starting review of an application only when a reasonably complete application has been received. The Commission has developed a standard format for applications which should enable applicants to present an initial application in reasonably complete form. (Notice was given of this standard format in the FEDERAL REGISTER of March 2, 1972, 37 F.R. 4375.) Accordingly, § 2.101 has been amended to provide that each application (accompanied by any required Environmental Report and application fee) will be initially treated as a tendered application to allow a determination as to whether it is reasonably complete and conforms to the Commission's requirements. That determination will generally be made within a period of 30 days. If not returned to the applicant by the end of that period, it will be docketed. The regulatory staff will thus be in a better position to establish a schedule for its review of the application and to specify the key intermediate points of that review. In construction permit and operating license proceedings, the appropriate notices (a notice of hearing in a construction permit proceeding; a notice of opportunity for hearing in an operating license proceeding) would be issued as soon as practicable after the application is docketed, to provide potential intervenors a better opportunity for more meaningful participation in the hearing process.

2. *Discovery* (including depositions, production of documents, and interrogatories). The amendments expand the time available for legitimate discovery by the parties to the proceeding and are expected to obviate or lessen the delays which the current discovery process has caused. Sections 2.740, 2.740a, 2.740b, and 2.741 follow the Federal rules of Civil Procedure, as revised in 1970, by providing for production of documents, serving of interrogatories and taking of depositions without the necessity of motions and orders by the presiding officer or the Commission. Such discovery will not be permitted until the matters in controversy have been preliminarily identified. Applicants are, however, encouraged to make available to interested persons any documents relied on in the application before that time. Once the matters in controversy have been identified, discovery will be limited to those matters following the initial prehearing conference (described in Item 4 below). Discovery is required to be completed before the second prehearing conference, except for good cause shown.

The amendments also liberalize the AEC rules considerably to provide for disclosure of more AEC documents as a matter of course. With respect to such documents, those that are relevant to the proceeding will generally be publicly available as a matter of course unless there is a compelling justification for their nondisclosure (§ 2.790). Therefore, document discovery directed at the staff will be tightly restricted. Since the routinely available documents should under this approach, reasonably disclose the basis for the staff's position, staff directed discovery can be limited to information concerning a matter necessary to a proper decision in the case and not obtainable elsewhere (§ 2.744). It should also be noted that with respect to documents, pertaining to licensing or rule making, filed with the Commission that are deemed to be proprietary in nature, the Commission will, in deciding whether the document should be withheld from disclosure, attempt to achieve an effective balance between the legitimate concerns of the person requesting withholding and the public interest in disclosure.

3. *Intervention.* The present procedures for intervention (which stem from statutory requirements) are essentially retained, but certain new responsibilities are placed on those permitted to intervene in connection with making and supporting allegations on matters they seek to place in controversy for hearing consideration. The opening up of the process, as described above, implies that intervenors should have correlative responsibilities to help define and substantiate the matters that they seek to put in issue after they have had an opportunity to avail themselves of the information that would then be open to them. Definition of the matters in controversy is widely recognized as the keystone to the efficient progress of a contested proceeding. In order to put a matter in issue, it will not be sufficient merely to make an unsupported allegation. Orders permitting intervention can be conditioned to restrict irrelevant, duplicative, or repetitive evidence and argument and to require common interests to be represented by a spokesman. It will also be possible to limit an intervention to one or more issues upon a finding that the petitioner's interest is so limited.

4. *Prehearing conferences.* The amendments to Part 2 also provide for a special prehearing conference to be held within 60 days after the notice of hearing on an application for a facility construction permit is published, or such other time as the Commission or the presiding officer may deem appropriate. In an operating license proceeding in which a hearing is requested, the date would ordinarily be specified when the Commission ruled on the request. This conference would be in addition to, and not in place of, the prehearing conference contemplated by § 2.752 of Part 2. The purpose of the special conference is to permit identification of key issues; consider petitions for leave to intervene in order to allow preliminary or final determinations as to the parties to the proceeding; provide for the submission of status reports on discovery; and establish a schedule for further actions in the proceeding. Further, informal conferences, including telephone conferences, can be held to the extent they would expedite the proceedings. The second prehearing conference, held pursuant to existing § 2.752, as amended, will usually be held within 60 days after discovery has been completed. "Discovery," for this purpose, does not include production of the report of the Advisory Committee on Reactor Safeguards, the AEC staff safety evaluation or the AEC detailed statement on environmental considerations.

5. *Consolidation of parties.* A new § 2.715a has been added to Part 2 to provide that, if more than one party has substantially the same kind of interest that may be affected by the proceeding, and raises the same basic questions, the presiding officer or the Commission may order those parties to consolidate their presentation of evidence, cross-examination, briefs, proposed findings, and conclusions of law and argument, unless the consolidation would prejudice the rights of any party. Depending on the circumstances, the consolidation could be effected across-the-board on all issues or selectively with respect to one or more issues.

6. *Limitation of issues in operating license hearing.* At the operating license stage, where a hearing is required only upon the request of a person whose interest may be affected, the issues in a proceeding will be limited to matters that are actually put in controversy by the parties. Thus, if radiation safety matters were not put in issue, they would not be considered at the hearing. Under this approach, the atomic safety and licensing board or other presiding officer will not make the findings on the traditional, ultimate issues, but will make findings only on the matters in controversy, and, depending on the resolution of those matters, the Director of Regulation, after making the requisite findings, will issue, deny, or appropriately condition the license.

7. *Improvements in the public hearing process.* (a) Stricter requirements for granting of late petitions for leave to intervene have been added to § 2.714. Nontimely filings will not be entertained absent a determination that the petitioner had made a substantial showing of good cause for failure to file on time.

(b) *Limitations on time allotted for conduct of hearing.* Many of the time limitations prescribed by the current rules were set to allow the maximum time for the parties to the proceedings to perform various activities. There are instances where the activities covered by the limitations can be performed in much less time. In appropriate cases where it would not prejudice a party, the presiding officer is authorized to reduce the time limits by order. Similarly, in any instance where a time limit is not set by regulation, the presiding officer is authorized to impose reasonable time limits.

(c) *Advance written testimony.* The use of advance written testimony by all parties is now required by amendment of § 2.743 and can be expected to expedite the hearing process as well as to provide other benefits. Counsel and their technical advisers can examiner the material before hearing and be prepared to cross-examine without delay. (Persons who wish to make a limited appearance, and a statement in connection therewith, will, of course, be permitted to do so.)

(d) *Summary disposition on pleadings.* Courts for many years have recognized and used the device of deciding certain matters, such as questions of law, on the pleadings. In many cases, argument and further hearing can add nothing to the filings in the proceeding. In those cases the presiding officer should be able, on motion, to render a decision, if the filings in the proceeding and other materials show that there is no genuine issue as to any material fact. A new § 2.749 permits such summary disposition. However, in any proceeding involving a construction permit where a hearing is required by law, this procedure can be used only for determining subordinate issues and not the ultimate issue as to whether the permit should be issued.

(e) *Authority of presiding officers to regulate hearings.* Most opportunities for expediting proceedings occur during the hearing phase. Delinquencies occurring in this phase will compound delays in the final phase. The effectiveness of the presiding officer depends not only on his ability to organize and manage, but also on the tools he is given. Therefore, to prevent unnecessary delays and an unnecessarily large record, the presiding officer is authorized to limit cumulative testimony, strike argumentative, repetitious, cumulative, or irrelevant evidence, take necessary and proper steps to prevent argumentative, repetitious, and cumulative cross-examination, and impose reasonable time limits on arguments.

(f) *Consideration of AEC rules in hearings in licensing proceedings.* In view of the expanding opportunities for participation in Commission rule making proceedings and increased emphasis on rule making proceedings as the appropriate forum for settling basic policy issues, new § 2.758 provides that challenges to Commission regulations in quasi-adjudicatory proceedings involving initial licensing shall be restricted to the matter of whether the application of a specified regulation or provision thereof should be waived or an exception made for the particular proceeding because special circumstances with respect to the subject matter of the particular proceeding are such that the application of the regulation would not serve the purposes for which it was adopted.

Whenever a party wishes to take such a position, he is required to file a petition and furnish particulars by affidavit. Upon a finding by the presiding officer, based on the affidavits and any material in response submitted by other parties, that the asserting party has not made a prima facie case, no evidence, discovery, or argument will be allowed on the matter. If the presiding officer finds that such a showing has been made, he will certify directly to the Commission for determination the question of whether the application of the Commission regulation to a particular aspect of the subject matter of the proceeding should be waived or an exception made. The provision does not apply in instances where a challenge to Commission regulations had been made, and a ruling rendered, before the effective date of the new section.

(g) *Official notice.* The provisions of amended § 2.743 of Part 2 pertaining to official notice require the specification in the record of each fact of which the Commission and the presiding officer take official notice, with sufficient particularity to advise the parties of what facts have been noticed. There will be opportunity for each party adversely affected by the decision to controvert the fact. It is expected that the amendment will clarify the scope of "official notice" while preserving the legitimate use of the technique to eliminate the need for introduction of evidence on facts properly falling within "official notice".

(h) *Encouraging stipulations and authentication of documents through prehearing conferences.* At the second prehearing conference, parties will be encouraged to stipulate uncontroverted material, thus making possible the elimination of a substantial amount of cross-examination and the saving of time and expense. Stipulations as to procedure are also permitted. Further, stipulations are encouraged at all later procedural stages.

(i) *Recognition of public interest in fair and reasonable settlements.* Formal recognition has been given to the public interest in achieving fair and reasonable settlement of contested proceedings. To the extent not inconsistent with the hearing requirement in section 189 of the Act (42 U.S.C. 2239), such settlements are encouraged, either as to particular issues in a proceeding or the entire proceeding. It is expected that the presiding officer and all the parties to the proceeding will take appropriate action to carry out this purpose.

(j) *Informal conferences.* Greater emphasis is placed on the use of informal conferences among the parties (including telephone conferences) to expedite proceedings.

(k) *Time for regulatory staff to respond to motions and petitions and to file other papers in adjudicatory proceedings.* The amendments to Part 2 allow the regulatory staff an opportunity to consider all matters and positions taken by other parties before finalizing its position on various questions presented during a proceeding. The affording of this opportunity to the staff is considered appropriate in view of its duty to represent the public interest in Commission adjudicatory proceedings and to assure the development of an adequate decisional record. The staff is allowed to file answers to motions, proposed findings of fact, and conclusions of law, exceptions to initial decisions and briefs in support of or in opposition to exceptions filed by another party, and answers to petitions for leave to intervene and for reconsideration 5 days later than the time specified for filing of those documents by other parties to a proceeding.

(l) *Limitations on use of expert interrogators.* Section 2.733 has been amended to require the presiding officer to make a determination that an individual other than an attorney whom a party wishes to conduct on his behalf examination or cross-examination of witnesses has appropriate scientific or technical qualifications, that such individual has read any written or oral testimony or any documents that will be the subject of examination, and that he has prepared himself to conduct a meaningful and expeditious examination or cross-examination. Permission to conduct examination will be limited to the areas in which the interrogator has been shown to be qualified. The party on whose behalf the interrogator conducts the examination and his attorney will be held responsible for the interrogator's conduct of examination or cross-examination. The use of such expert interrogators will be permitted for the purpose of furthering the conduct of the proceeding.

Certain changes have been made in Part 2 to reflect the provisions of Appendix D of Part 50 that are applicable to hearings held on applications for facility construction permits or operating licenses. Other changes to Part 2 have also been made. The latter category includes amendments to §§ 2.105 and 2.106 of Part 2 which conform the provisions of those sections to the present requirements of the Atomic Energy Act and to the Commission's practice, and modify the provisions for publication of notice of the issuance of licenses. Amendments to Appendix A of Part 2 modify the statement therein of the Commission's policy of holding hearings in the vicinity of the facility to provide for the holding of hearing sessions in the Washington, D.C. area in cases in which all parties so stipulate or when valid reasons for such location exist.

To reflect the changes discussed above, and the fact that most hearings in facility licensing proceedings are now contested proceedings, Appendix A of Part 2 has been extensively revised.

The Commission recognizes that some of the provisions of the amendments which follow will not be appropriate for application to pending proceedings in various stages. They will be applied as appropriate when the context so indicates. For example, petitions for leave to intervene that were filed without an accompanying affidavit before the effective date of the amendments will not be denied for that reason.

The time allowed State and local agencies and interested members of the public for comment on the Applicant's Environmental Report and the AEC draft Detailed Statement has been changed to forty-five (45) days, conforming to the time allowed Federal agencies.

Section C of Appendix D has been amended to provide that, in a licensing proceeding subject to that section, if construction of the facility is expected to be completed by or soon after the completion of the NEPA environmental review required by that section, the NEPA environmental review will cover both the construction permit and the operating license stages. One notice of opportunity for hearing will be issued, and, upon publication of such a notice, the provisions of section D, including sections D.2 and 3, will be applicable.

Pursuant to the National Environmental Policy Act of 1969, the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter 1, Code of Federal Regulations, Parts 2, 9, and 50 are published as a document subject to codification to be effective 30 days after publication in the FEDERAL REGISTER.

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37 FR 17159
Published 8/25/72
Effective 8/25/72

Delegation of Certain Authority to Specified Members of the Atomic Safety and Licensing Appeal Board

The Atomic Energy Commission's rules of practice, 10 CFR Part 2, provide for the establishment of an Atomic Safety and Licensing Appeal Board to exercise the authority and perform the review functions which would otherwise have been exercised and performed by the Commission in certain licensing proceedings. The Appeal Board's authority includes action on procedural matters, including requests for stays of licensing board orders.

Under the rules of practice, two members of the Appeal Board constitute a quorum, if one of those members is qualified in the conduct of administrative proceedings; and the vote of a majority controls in any decision by the Appeal Board, including orders in interlocutory matters. (See 10 CFR Part 2, Appendix A, VII(b).) The Commission has amended its rules of practice to permit designated individuals to act for the Appeal Board on procedural matters, including requests for stays of licensing board orders, in the absence of a quorum. Action by a designated individual under this authority shall be reviewable by the Appeal Board, except that with respect to requests of stays of licensing board orders, such action shall be reviewable by the Commission. All other actions under this authority may also be reviewed by the Commission under the standards of § 2.786.

Since the amendments which follow relate solely to matters of internal management, and are procedural rather than substantive, the Commission has found that general notice of proposed rule making and public procedure thereon are unnecessary, and that good cause exists to make the amendments effective upon publication in the FEDERAL REGISTER.

Pursuant to the Atomic Energy Act of 1954, as amended, and section 552 and 553 of title 5 of the United States Code, the following revisions to Title 10, Chapter 1, Code of Federal Regulations, Part 2, are published as a document subject to codification, to be effective upon publication in the FEDERAL REGISTER (8-25-72).

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37 FR 22791
Published 10/25/72
Effective 10/25/72

Delegation of Authority to Atomic Safety and Licensing Appeal Panel; Assignment and Change in Composition of Atomic Safety and Licensing Appeal Boards

Under the Atomic Energy Commission's rules of practice, the Atomic Safety and Licensing Appeal Board has been directed to exercise the authority and perform the review functions which would otherwise have been exercised and performed by the Commission in such licensing proceedings as the Commission may specify, as well as in specified categories of proceedings arising under Parts 115 and 50. Since establishment of the

Appeal Board, the Commission has delegated its authority to the Appeal Board in every proceeding arising under Part 50. After considering its experience under this system, the Commission has modified its rules to delegate authority to the Appeal Board in all proceedings under Part 50. The Commission will retain the review authority provided in 10 CFR 2.786.

Under the rules of practice, the Appeal Board is currently composed of the Chairman of the Appeal Board, the Vice Chairman of the Appeal Board, and a third member designated by the Commission for each proceeding; except that in proceedings involving antitrust considerations it is composed of the Chairman and two members designated by the Commission possessing qualifications appropriate to the issues to be decided. Heretofore, the Appeal Board in other than antitrust proceedings has included two technical members—the Vice Chairman and a member designated by the Commission.

Because of the increasing caseload of the Appeal Board, and the resulting burden in requiring the Chairman to sit on every case, and the Vice Chairman to sit on all except antitrust cases, the Commission has provided an expanded organizational framework for the Appeal Board, by establishing an Atomic Safety and Licensing Appeal Panel, from which will be selected members to sit on particular cases. The composition of the Appeal Board for a particular proceeding has been modified so that it will include three members possessing qualifications deemed appropriate to the issues to be decided. The Chairman of the Appeal Board for a particular proceeding shall be qualified in the conduct of administrative proceedings.

The activities of the Appeal Panel will be supervised by a permanent Chairman and, in his absence, by a permanent Vice Chairman. Members of the Panel will be designated by the Commission, but the members of the Appeal Board for a particular proceeding will be assigned by the permanent Chairman or, in his absence, by the permanent Vice Chairman.

To reflect the above-mentioned increasing caseload, the Commission has also amended 10 CFR 2.786 to expand the the time within which the Commission may exercise its review authority under that section from 15 days to 20 days.

The amendments incorporate various technical changes to accommodate the above-described organizational changes.

Because the amendments relate to agency management, and are procedural rather than substantive, notice of proposed rule making and public procedure thereon are not required by section 553 of title 5 of the United States Code.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Parts 1 and 2, are published as a document subject to codification, to be effective upon publication in the FEDERAL REGISTER (10-25-72).

37 FR 24736
Published 11/21/72
Effective 12/21/72

Time for Filing Proposed Findings of Fact and Conclusions of Law

The Atomic Energy Commission has adopted an amendment to its rules of practice, 10 CFR Part 2, pertaining to the time within which parties to an adjudicatory proceeding must file proposed findings of fact and conclusions of law after the close of the record.

The rules of practice now provide § 2.754 for the filing of such proposed findings and conclusions and briefs within 20 days after the record is closed by the party who has the burden of proof, such as a license applicant. Other parties then have 20 days thereafter to file proposed findings and conclusions and briefs, except that the regulatory staff has 25 days. The party who has the burden of proof may reply within 10 days after service of proposed findings and conclusions and briefs by other parties.

Section 2.754 has been amended to provide that the party who has the burden of proof shall file proposed findings of fact and conclusions of law and briefs within 15 days after the close of the record, while other parties, except the regulatory staff, may file such proposed findings and conclusions and briefs within 25 days after the close of the record. The regulatory staff has 30 days after the close of the record to file proposed findings and conclusions and briefs. The party who has the burden of proof may reply within 5 days after service of the proposed findings and conclusions and briefs of the other parties. Conforming amendments have been made to appendix A of Part 2. The amendments are expected to result in greater expedition in Commission adjudicatory proceedings without impairing the rights of any party.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 2, are published as a document subject to codification to be effective 30 days after publication in the FEDERAL REGISTER.

37 FR 28710
Published 12/29/72
Effective 12/29/72

Authority of Atomic Safety and Licensing Board to Rule on Certain Petitions

Section 191 of the Atomic Energy Act of 1954, as amended (42 U.S.C. section 2011 et seq.) provides for the establishment of atomic safety and licensing boards to conduct hearings and make initial decisions with respect to the granting, suspending, revoking, or amending of licenses or authorizations under the Atomic Energy Act and other law. This includes proceedings to consider applications for construction permits or operating licenses for production or utilization facilities.

Under the existing rules of practice (10 CFR Part 2), a proceeding for a construction permit for a facility is initiated by the issuance of a notice of hearing signed by the Secretary of the Commission, after the application has been docketed. Any petitions for intervention or limited appearance filed with the Commission are ruled on by the atomic safety and licensing board designated to preside over the hearing, generally at a special prehearing conference held within sixty (60) days after the notice of hearing has been published. In contrast, a proceeding for an operating license for a facility starts with a notice of consideration of issuance of facility operating license and opportunity for hearing. In such proceedings, any petitions for intervention and hearing are ruled on by the Commission. Where warranted, the Commission orders a hearing and issues a notice of hearing.

The Commission has amended its rules of practice to permit atomic safety and licensing boards to assume the function of ruling on petitions for intervention and hearing in operating license proceedings. This function may be exercised either by a board designated for a particular operating license proceeding or by a board designated to rule on such petitions. If the board orders a hearing, it will issue an appropriate notice stating the nature of the hearing, the issues to be considered, and any other matter which the board considers to be appropriate.

Appeals from licensing board rulings on petitions for intervention and/or hearing in construction permit or operating license proceedings are permitted in specified circumstances. Any board order wholly denying a petition for intervention and/or hearing is appealable by the petitioner on the question whether the petition and/or hearing request should have been granted in whole or in part. Any board order granting a petition for intervention and/or hearing is appealable by a party other than the petitioner on the question whether the petition and/or request for a hearing should have been wholly denied. Any appeal must be made within 5 days of the appealable order.

Since the amendments which follow relate solely to matters of internal management, and are procedural rather than substantive, general notice of proposed rule making and public procedure thereon are not required by section 553 of title 5 of the United States Code.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of title 5 of the United States Code, the following revisions to Title 10, Chapter 1, Code of Federal Regulations, Part 2, are published as a document subject to codification, to be effective upon publication in the FEDERAL REGISTER (12-29-72).

38 FR 1500
Published 1/15/73
Effective 1/15/73

Definition of "AEC Personnel"

The Atomic Energy Commission has adopted an amendment to its rules of practice in 10 CFR Part 2 which refines the definition of "AEC personnel" as used in that part.

Section 2.4 of Part 2 now includes within the definition of "AEC personnel," persons who are "consultants * * * of the AEC." In order to clarify the scope of the term "consultants * * * of the AEC," the amendment adopted specifically includes within that definition persons who are acting in the capacity of consultants to the Commission, regardless of the form of the contractual arrangements under which such persons render consultant services.

Thus, employees of AEC contractors are included in the definition of AEC personnel (for §§ 2.270 and 2.740 purposes only) to the extent that they act as consultants to the Commission, even though there is no special contract for consulting services between the Commission and such employees.

The clarification of the definition in § 2.4 has the effect of making applicable to employees of AEC contractors and other persons acting as consultants to the Commission, regardless of the form of the contractual arrangements, § 2.270 (h), which deals, inter alia, with attendance and testimony of "AEC personnel."

Since the amendment which follows relates to rules of agency procedure and practice, notice of proposed rule making and public procedure thereon are not required by section 553 of Title 5 of the United States Code and the amendment may be made effective without the customary 30 day notice.

Effective date. Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendment to Title 10, Chapter 1, Code of Federal Regulations, Part 2, is published as a document subject to codification, to be effective on January 15, 1973.

38 FR 2330
Published 1/24/73
Effective 1/24/73

Miscellaneous Amendment

A rule changing the title "hearing examiner" to "administrative law judge" was published by the U.S. Civil Service Commission in the FEDERAL REGISTER on August 19, 1972 (37 FR 16787).

The Atomic Energy Commission's regulations in 10 CFR Parts 1, 2, and 4 contain numerous references to the terms "Office of Hearing Examiners", "hearing examiner", "hearing examiners", and "Chief Hearing Examiner".

These references should be changed to conform with the action of the U.S. Civil Service Commission on August 19, 1972, and to be consistent with other regulatory agencies in using the title "administrative law judge".

The Commission intends to revise Form AEC-741. Among the minor changes the title will be changed from "Nuclear Material Transfer Report" to "Nuclear Material Transaction Report". The amendments of Parts 30, 40, 70, and 150 reflect the new title of Form AEC-741.

Inasmuch as the amendments set forth below relate to agency management and organization, correction, and minor procedural matters, notice of proposed rule making and public procedure thereon are not required by section 553 of title 5 of the United States Code.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Parts 1, 2, 4, 30, 40, 70, and 150 are published as a document subject to codification, to be effective on January 24, 1973.

38 FR 5624
Published 3/2/73
Effective 3/2/73

Appellate Consideration of Exceptions to Initial Decisions

Section 2.762 of the Atomic Energy Commission's rules of practice, 10 CFR Part 2, sets forth procedures for the filing by parties of exceptions to initial decisions, and supporting briefs, in adjudicatory proceedings, including licensing proceedings. Because of the growing number and complexity of these proceedings, the Commission has adopted certain amendments to § 2.762, as well as to Appendix A of Part 2, designed to improve these appellate procedures. The revisions provide for the separate filing of exceptions and briefs and establish additional standards respecting the form and content of these documents. It is the Commission's expectation that these changes will be utilized to improve the product which is filed with the Commission, and thereby to expedite the resolution of issues on appeal. The Commission will continue to evaluate the effectiveness of its appellate procedures in achieving these results and will consider such further modifications as may be desirable in this regard.

Because the amendments relate to matters of procedure and practice, notice of proposed rulemaking and public procedure thereon are not required by section 553 of title 5 of the United States Code.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 2, are published as a document subject to codification. The amendments shall be effective on March 2, 1973, and shall be applicable to initial decisions rendered on or after that date.

38 FR 9585
Published 4/18/73
Effective 4/18/73

Licenses, Facility Construction Permits, and Operating Licenses

The Atomic Energy Commission has adopted amendments to its rules of practice in 10 CFR part 2 and to 10 CFR part 50, Licensing of Production and Utilization Facilities, that (1) conform the criterion for 30-day prior notice of amendments to facility construction permits and operating licenses more precisely to the terms of the Atomic Energy Act and (2) provide for publication of notices of issuance of amendments of certain licenses whether or not notices of the proposed action had been published.

Section 189 of the Atomic Energy Act of 1954, as amended (the Act), provides that in cases where a construction permit for a facility under sections 103 or 104 b. of the Act, or a testing facility under section 104 c. of the Act, has been issued following a hearing, the Commission may, in the absence of a request therefor by any person whose interest may be affected, issue an amendment to the construction permit or to the operating license without a hearing, upon 30-days' notice and publication of its intent to do so in the FEDERAL REGISTER, except that that notice may be dispensed with upon a determination that the amendment does not involve a significant hazards consideration.

In implementation of § 189, part 2 contains provisions which state that a notice of proposed action on an amendment to a facility license which "involves significant hazards considerations different from those previously evaluated" will be published in the FEDERAL REGISTER, and will provide that, within 30 days from date of publication of the notice or such lesser period authorized by law, the applicant may request a hearing or any person whose interest may be affected by the proceeding may file a petition for leave to intervene (§ 2.105). Section 2.106 provides for notice, by publication in the FEDERAL REGISTER, of the issuance of amendments to facility licenses for which a notice of proposed action has been previously published, among other things.

The amendments which follow express the criterion for publication of 30-day prior notice of proposed action on amendments to facility licenses (including construction permits) in § 2.105 of part 2 and a related section of part 50 in the same terms as the criterion of section 189 a. of the Act, i.e., the involvement of "a significant hazards consideration" rather than "significant hazards considerations not previously evaluated."

In addition, § 2.106 of part 2 has been amended to provide for publication of notice of issuance of an amendment of a facility construction permit or operating license, in the case of a facility of the type described in § 50.21(b) or § 50.22 of part 50 or a testing facility, whether or not a notice of proposed action on the amendment had been published.

The Commission has found that since to the extent these amendments relate to matters other than procedural matters, they are of a minor, clarifying nature, good cause exists for omitting notice of proposed rulemaking and public procedures thereon as unnecessary, and for making the amendments effective without the customary 30-day notice.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, parts 2 and 50 are published as a document subject to codification, to be effective on April 18, 1973.

38 FR 30251
Published 11/2/73
Effective 12/3/73

STANDARDIZATION OF DESIGN; LICENSES TO MANUFACTURE NUCLEAR POWER REACTORS

Miscellaneous Amendments

On April 25, 1973, the Atomic Energy Commission published in the FEDERAL REGISTER (38 FR 10158) proposed amendments to its regulations in 10 CFR Part 2, "Rules of Practice;" Part 50, "Licensing of Production and Utilization Facilities;" and Part 170, "Fees for Facilities and Materials Licenses Under the Atomic Energy Act of 1954, As Amended." The proposed amendments would change the

Commission's existing regulations to accommodate an approach to standardization of reactor design that would provide for licensing the manufacture at an industrial location of several nuclear power reactors of standard design to be operated at sites not identified in the application for the license to manufacture. The rules would cover such applications as applications for the manufacture of barge-mounted reactors that are subsequently installed and operated at ocean sites.

Interested persons were invited to submit written comments and suggestions for consideration in connection with the proposed amendments by June 11, 1973. After consideration of the comments received and other factors involved, the Commission has adopted the proposed amendments with certain modifications, in the form set forth below.

Significant differences from the amendments published for comment are:

1. Paragraph 4. of Appendix M of Part 50 has been modified to provide that certain requirements of Appendix E of Part 50 pertaining to plans for coping with emergencies in the operation of a facility which involve facility design features are applicable to manufacturing licenses and a conforming amendment has been made to paragraph 2. of Appendix M.

2. Paragraph 5. of Appendix M of Part 50, which specifies the findings which must be made by the Commission for the issuance of a manufacturing license, has been modified to require a finding, among others, that there is reasonable assurance that any unresolved safety questions will be resolved before any of the nuclear power reactors to be manufactured pursuant to the license are removed from the manufacturing site.

3. The fees for manufacturing licenses and construction permits for power reactors for which a manufacturing license has been issued have been revised to be consistent with the revised schedule of license fees published by the Commission on July 11, 1973 (38 FR 18443).

Other changes reflecting additions to Part 50 since publication of the proposed amendments and certain clarifying changes have also been made.

The amendments which follow contemplate the manufacture of several nuclear power reactors of standard design at an industrial location. The reactors thus manufactured will eventually be located and operated at utility sites. Some of these sites may be ocean sites, created by the construction of breakwaters, at which previously manufactured barge-mounted reactors could be installed and operated. The manufacture of these reactors requires the issuance of a Commission license to the manufacturer, after review of the application by the Commission's regulatory staff and the Advisory Committee on Reactor Safeguards and the holding of a public hearing. A construction permit from the Commission is required of the utility prior to the commencement of necessary construction at the utility site to accommodate the reactor and prior to the transport of the reactor to, and its installation at, that site. A Commission license is, of course, also required for the operation of the reactor.

Under the amendments set forth below, which relate to matters of radiological health and safety, environmental protection and the common defense and security, an applicant for a license to manufacture nuclear power reactors pursuant to a new Appendix M of Part 50 is required to include in his application, in addition to design information, the postulated site parameters.

Such an applicant is also required to submit an environmental report discussing the environmental effects of the manufacture of the reactors and, in general terms, the environmental effects of their installation and operation at an hypothesized site or sites having characteristics that fall within the postulated site parameters.

A manufacturing license, if issued, will authorize manufacture of a specified number of reactors. Once the final standardized design is developed by the holder of a license to manufacture, the holder must request approval of the final standardized design by submitting an application for amendment of the license to manufacture. An opportunity for hearing will be provided in connection with the application for license amendment. Applications to amend a manufacturing license to authorize manufacture of additional units could, of course, be submitted.

In the construction permit proceeding, the focus will be on the specific site chosen by the utility applicant, including whether that site falls within the postulated site parameters specified at the manufacturing license stage. In cases where a manufacturing license is sought, no construction permit will be issued to the utility until after the manufacturing license has been issued to the manufacturer. The environmental report required of the utility applicant will not be expected to duplicate matters covered in the environmental report submitted in connection with the application for a manufacturing license.

One of the major purposes of the amendments is the elimination of unnecessary duplication in the review process. Accordingly, the amendments provide that matters resolved at any stage of the licensing process will, in general, not have to be reconsidered at subsequent stages of that process. The Commission may, however, reopen matters previously resolved in the licensing process on the basis of significant new information that substantially affects the conclusion(s) reached at the earlier stage or other good cause.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendments of 10 CFR Parts 2, 50, and 170 are published as a document subject to codification.

39 FR 12353
Published 4/5/74
Effective 4/5/74

Requests To Impose Requirements by Order on a Licensee, or To Modify, Suspend or Revoke a License

The Atomic Energy Commission has adopted amendments to its Rules of Practice in 10 CFR Part 2, that make specific provision for members of the public to request the Director of Regulation to institute a proceeding to modify, suspend or revoke a license, or take such other action as may be proper. Under existing rules such requests are not precluded, though there is no specific provision therefor. The purpose of the amendments is to provide a procedure for the submittal of such requests to the Director of Regulation.

The amendments add new § 2.206 that provides for the filing of a request addressed to the Director of Regulation to modify, suspend or revoke a license, or take such action as may be proper.

Upon the filing of such a request, the Director of Regulation may institute the requested proceeding, or advise the person who filed the request that no proceeding will be instituted and the reasons therefor.

Unless otherwise directed by the Commission, any request for modification, suspension or revocation of a license, or for other like action, will be referred to the Director of Regulation and processed pursuant to new § 2.206.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 2 are published as a document subject to codification.

39 FR 14506
Published 4/24/74
Effective 4/24/74

Pre-Construction Permit Activities

See Part 50 Statements of Consideration

39 FR 17972
Published 5/22/74
Effective 5/22/74

Miscellaneous Amendments to Chapter

Notice is hereby given of the amendment of the Atomic Energy Commission's regulations in 10 CFR Parts 2, 20, 50, and 73.

The amendments of Part 2 amend § 2.104(e) to provide that the Secretary of the Commission, rather than the Director of Regulation, will transmit copies of the notice of hearing to State and local officials in accordance with the provisions of § 2.104(e). Section 2.700 is amended to clarify that the scope of Subpart G—Rules of General Applicability, includes rules governing procedure in adjudications initiated by issuance of a notice pursuant to § 2.102(d)(3) regarding the antitrust aspects of the application. A minor editorial change also is made in § 2.714.

Appendix D of Part 20 and Appendix A of Part 73 are amended to list the new daytime telephone number for the Region V office, Directorate of Regulatory Operations.

Section 50.30(c)(2) of Part 50 is amended to clarify that any amendments to the application served on the hearing board after the proceeding has been noticed must be filed also in the regular manner for filing such amendments with the Director of Regulation.

Inasmuch as the amendments set forth below are of a minor nature or are procedural and clarifying changes, notice of proposed rule making and public procedure thereon are not required by section

553 of title 5 of the United States Code, and the Commission has found good cause for making the amendments effective May 22, 1974.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Parts 2, 20, 50, and 73 are published as a document subject to codification.

39 FR 24219
Published 7/1/74
Effective 7/1/74

Delegation of Certain Authority to the Secretary of the Commission

The Atomic Energy Commission's statement of Organization and General Information (10 CFR 1.13), describes in general terms the duties and authority of the Secretary of the Commission. The Secretary's responsibilities include assisting the Commission in the scheduling and conduct of its business. Pursuant to this authority, the Secretary occasionally acts for the Commission on procedural matters arising in connection with the Commission's role in adjudicatory and rulemaking proceedings.

Because clarification of the Secretary's authority with respect to procedural matters is desirable, the Commission has amended its Rules of Practice to specify in greater detail the Secretary's authority to act on procedural aspects of various matters arising in connection with adjudicatory and rulemaking proceedings after consulting with the General Counsel or, where appropriate, with the Solicitor. The Secretary's authority includes, but is not limited to, establishment of schedules for filing of briefs, motions, responses or other pleadings, where such schedules differ from those presented elsewhere in the rules of practice; ruling on motions for extension of time; and issuance of orders concerning oral arguments in any proceeding where the Commission has determined that an oral argument will be held.

Since the amendments which follow concern rules of agency procedure and practice, the Commission has found that general notice of proposed rulemaking and public procedure thereon are unnecessary, and that good cause exists to make the amendments effective July 1, 1974.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter 1, Code of Federal Regulations, Part 2, are published as a document subject to codification.

39 FR 26279
Published 7/18/74
Effective 8/19/74

Environmental Protection: Licensing and Regulatory Policy and Procedures

See Part 51 Statements of Consideration.

39 FR 35332
Published 10/1/74
Effective 10/1/74

Miscellaneous Amendments

Notice is hereby given of amendments to 10 CFR Part 2 of the Atomic Energy Commission's regulations.

The amendments pertain to the addressing of communications, documents, and pleadings in adjudications subject to Part 2. The amendments reflect changes which have occurred in the organization of the Office of the Secretary of the Commission and provide for the addressing of communications.

Because these amendments relate solely to agency organization, notice of proposed rule making and public procedure thereon are not required by section 553 of Title 5 of the United States Code.

Accordingly, pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendments of Part 2 of the Commission's regulations are published as a document subject to codification.

39 FR 43195
Published 12/11/74
Effective 1/10/75

PART 2—RULE OF PRACTICE

Denial of Application Procedure

Under the Commission's regulations in 10 CFR 2.108 the Director of Regulation may deny an application if the applicant fails to respond to a request by the regulatory staff for additional information. Notice of such a denial is required to be published in the FEDERAL REGISTER when a notice of receipt of the application has previously been published. The notice must provide that within thirty days, the applicant may demand a hearing and any person whose interest may be affected may file a petition for leave to intervene. Where the notice of hearing has not yet been published, the procedure set forth in the present § 2.108 appears satisfactory. However, in instances where a notice of hearing has already been published, there does not appear to be any need for a separate notice in the FEDERAL REGISTER as provided by § 2.108(b). A more appropriate procedure under these circumstances would be for the presiding officer to determine whether an application should be denied for failure to respond to a request for information upon a motion made by the regulatory staff to deny the application on this ground. Accordingly, the Commission is amending § 2.108 to provide for such a procedure.

Since the amendments which follow relate to rules of agency procedure and practice, notice of proposed rulemaking and public procedure thereon are not required by section 553 of Title 5 of the United States Code. Accordingly, pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10 of the Code of Federal Regulations, Part 2, are published as a document subject to codification.

40 FR 2973
Published 1/17/75
Effective 2/18/75

PART 2—RULES OF PRACTICE

Discovery; Issues Not Raised by Parties

The Atomic Energy Commission has adopted amendments to its "Rules of Practice", 10 CFR Part 2. These amendments will (1) change Commission discovery procedures as they relate to the attendance and testimony of AEC personnel at hearings and staff responses to written interrogatories and (2) provide that while Atomic Safety and Licensing Boards are neither required not expected to look for new issues not raised by the parties, in extraordinary circumstances where a board determines that a serious safety, environmental, or common defense and security matter was not raised by the parties to a hearing, the board may exercise its discretion to examine and decide such matters; Atomic Safety and Licensing Appeal Boards may give appropriate consideration to such matters.

On July 16, 1974, the Commission issued a decision In the Matter of Consumers Power Company (Midland Plant, Units 1 and 2) in which it questioned whether the AEC regulations requiring interlocutory Commission review before a licensing board may order discovery involving Commission personnel and/or documents served any useful purpose. The Commission pointed out in its decision that these AEC regulations requiring interlocutory review can contribute to delay in adjudication, that in procedural matters the licensing boards have a better appreciation for all the circumstances surrounding a particular case, and that these regulations accord a preferential status to Commission personnel and documents while discriminating against other parties who cannot invoke Commission review of their refusal to respond to discovery.

To conform the regulations in Part 2 to this Commission decision, §§ 2.720(h), 2.744 (d) and (g), and paragraph IV(d) to Appendix A are amended, and § 2.744 (e) is deleted, to permit the presiding officer in his discretion to compel the attendance and testimony of AEC personnel and require the staff to answer written interrogatories. In either case the presiding officer may, in his discretion, determine that such action would place an unwarrantedly severe burden upon the AEC personnel whose attendance or written response is requested and on this basis disallow the discovery request.

On July 16, 1974 the Commission also issued a decision In the Matter of Consolidated Edison Company of New York (Indian Point Nuclear Generating Unit 3) in which it held that a licensing board has the authority to examine and decide issues which the board itself deems relevant even though the parties have not placed such matters in controversy. To conform the AEC regulations to this decision, §§ 2.104(c), 2.760a, 2.785, and sections VIII and IX of Appendix A to Part 2 are amended. When the presiding officer, such as an Atomic Safety and Licensing Board, determines in an operating license proceeding that a serious safety, environmental, or common defense and security issue exists that has not been raised by the parties to the proceeding, the presiding officer may examine and decide that issue. Atomic Safety and Licensing Appeal Boards may give appropriate consideration to such matters. However, this authority with respect to new issues not in controversy among the parties will be exercised sparingly and only in extraordinary circumstances.

Inasmuch as the amendments set forth below are procedural changes, notice of proposed rule making and public procedure thereon are not required by section 553 of title 5 of the United States Code.

Pursuant to the Atomic Energy Act of 1954, as amended, and section 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 2 are published as a document subject to codification.

40 FR 7893
Published 2/24/75
Effective 2/24/75

Implementation of the Freedom of Information Act

See Part 9 Statements of Consideration.

40 FR 8774
Published 3/3/75
Effective 3/3/75

ENERGY REORGANIZATION ACT

Revision of Chapter I To Reflect Organizational and Procedural Changes

On October 11, 1974, the Energy Reorganization Act of 1974, Pub. L. 93–438, was enacted.[1] That Act abolished the Atomic Energy Commission and created a new agency, the Nuclear Regulatory Commission (NRC), to which was transferred the licensing and related regulatory authority of the Atomic Energy Commission under the Atomic Energy Act of 1954, as amended. The Energy Reorganization Act also added, in section 202, authority for the NRC to license and regulate certain facilities owned by, and certain activities conducted by, the Energy Research and Development Administration (ERDA), which was also created by that Act.

The ERDA facilities and activities identified in section 202 are:

1. Demonstration Liquid Metal Fast Breeder reactors when operated as part of the power generation facilities of an electric utility system, or when operated in any other manner for the purpose of demonstrating the suitability for commercial application of such a reactor.
2. Other demonstration nuclear reactors, except those in existence on January 19, 1975, when operated as part of the power generation facilities of an electric utility system, or when operated in any other manner for the purpose of demonstrating the suitability for commercial application of such a reactor.
3. Facilities used primarily for the receipt and storage of high-level radioactive wastes resulting from licensed activities.
4. Retrievable Surface Storage Facilities and other facilities authorized for the express purpose of subsequent long-term storage of high-level radioactive waste generated by ERDA, which are not used for, or are part of, research and development activities.

The amendments set forth below reflect, in Chapter I of Title 10 of the Code of Federal Regulations, the division of the Atomic Energy Commission into two separate agencies, the organization of the NRC, the licensing and related regulatory authority of the NRC as to certain ERDA facilities and activities, and the prohibition against sex discrimination in Title IV of the Energy Reorganization Act. A separate document, published simultaneously in this issue (40 FR 8794), establishes the regulations of the Energy Research and Development Administration in 10 CFR Chapter III.

It should be noted that the NRC's authority over reactors within the first two categories specified in section 202 is reflected in Part 50, "Licensing of Production and Utilization Facilities," since reactors are utilization facilities licensed under that part, while the NRC's authority over the "facilities" in the latter two categories is reflected in Parts 30, 40 and 70, since those "facilities" are not production or utilization facilities within the definition of those terms in the Atomic Energy Act. Operators of ERDA-owned licensed reactors will be indemnified as licensees rather than as "ERDA contractors."

The existing exemptions for certain AEC contractors from licensing requirements has been continued for similar ERDA contractors, and a provision for exemptions for NRC contractors in appropriate cases has been added.

Part 7, Advisory Boards, has been revised to reflect the provisions of the Federal Advisory Committee Act (86 Stat. 770). Minor corrections to Chapter 1 have also been made.

Part 9, Public Records, has already been revised to reflect the 1974 Freedom of Information Act Amendments (Pub. L. 93–502) and the Energy Reorganization Act.

Section 301(b) of the Energy Reorganization Act of 1974 provides, in substance and as here pertinent, that the provisions of Chapter I of Title 10 of the Code of Federal Regulations are to continue in effect until modified by this Commission. The primary purpose of the technical and conforming amendments set forth below is to reflect wording, organizational and procedural changes effected or made necessary by that Act. These amendments, therefore, are primarily for the convenience of licensees, intervenors, and the interested public. Adoption of these technical amendments does not reflect any judgment by the Commission on the merits of the existing rules and is, of course, without prejudice to modification of those rules by the Commission in the future. These amendments will not affect any proceeding pending before the Atomic Energy Commission on the effective date of the Energy Reorganization Act of 1974. For these reasons, the Commission has found that notice of proposed rule making and public procedure thereon are unnecessary and that good cause exists for making the amendments effective on March 3, 1975.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, and sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter I of the Code of Federal Regulations are published as a document subject to codification.

40 FR 51995
Published 11/7/75
Effective 11/7/75

PART 2—RULES OF PRACTICE

Atomic Safety and Licensing Board Alternates

The Nuclear Regulatory Commission has adopted amendments to its "rules of practice", 10 CFR Part 2. These amendments specify the procedures for and delegate specific authority to the Chairman of the Atomic Safety and Licensing Board Panel in designating alternate Atomic Safety and Licensing Board members at all stages of the hearing process.

Section 2.704(a) gives the Commission the discretion to designate in the notice of hearing an Atomic Safety and Licensing Board (ASLB). If the Commission does not exercise this discretion, the Chairman of the ASLB Panel will issue an order designating an ASLB to preside. Section 2.721(a) gives both the Commission and the Chairman of the ASLB Panel the authority to establish ASLBs by designating members of the ASLB Panel established by the Commission.

Section 2.721 was ambiguous as to the appropriate action to be taken when an ASLB member might become unavailable. Section 2.721(b) gave the Commission sole discretion to designate alternate ASLB members even though § 2.721(a) permitted the Chairman of the ASLB Panel to designate the membership of an entire ASLB and § 2.721(b) gave the Chairman of the ASLB Panel sole discretion to constitute the alternate member in certain circumstances. Since the Commission has given the Chairman of the ASLB Panel the authority to designate the members of an ASLB, the Commission now has specifically delegated authority to the Chairman of the ASLB Panel to (1) appoint a qualified alternate at any time before, during, or after an ASLB hearing and (2) constitute the alternate, or in the event an alternate is unavailable or has not been designated, appoint a qualified alternate, to sit as a member of the board. The Commission will continue to have the discretion to designate qualified alternates if it so desires.

Section 2.704 currently contains provisions pertaining to the disqualification of a "presiding officer" on his own motion or that of a party. Clarifying language has been added to reflect current understanding and practice that these provisions apply to all members of a licensing board. In addition, this Section is revised to reflect that a motion to disqualify a Board member shall be referred to the Commission, or to the Atomic Safety and Licensing Appeal Board, as appropriate.

Inasmuch as the amendments set forth below are procedural changes, notice of

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[1] The effective date of The Energy Reorganization Act of 1974 is January 19, 1975.

proposed rulemaking and public procedure thereon are not required by section 553 of title 5 of the United States Code.

Pursuant to the Atomic Energy Act of 1954, as amended, section 201 of the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 2 are published as a document subject to codification.

41 FR 11808
Published 3/22/76
Effective 4/21/76

PART 2—RULES OF PRACTICE

Treatment of Trade Secrets and Confidential or Privileged Commercial or Financial Information

The Atomic Energy Commission published a notice in the FEDERAL REGISTER on November 22, 1974 (39 FR 40960) that it had under consideration an amendment of § 2.790, "Public inspections, exemptions, requests for withholding," of 10 CFR Part 2, "Rules of Practice." Interested persons were invited to submit written comments or suggestions for consideration in connection with the proposed amendment by January 21, 1975.[1] In response to several requests, the comment period was extended by the Nuclear Regulatory Commission (NRC) to February 20, 1975 (40 FR 4158). The comments on the proposed amendment having been given due consideration, there follows a discussion of those comments and the amendment to § 2.790 which has been adopted by the Commission.

Section 2.790 of 10 CFR provides that final NRC records and documents regarding certain licensing actions or rule making proceedings generally shall be made available for public inspection in the NRC Public Document Room. Paragraph (a) of § 2.790 of the proposed rule set forth categories of records which were to be exempted from disclosure, including "Trade secrets and commercial or financial information obtained from a person and privileged or confidential." The categories of information described in the proposed rule have been revised, however, to now conform them to the nine (9) categories specified in the Freedom of Information Act (5 U.S.C. § 552 (b)).

Paragraph (b) of § 2.790 sets forth a special procedure for exempting trade secret or other confidential or privileged commercial or financial information from public inspection. A person who proposes that NRC withhold a document from public disclosure on the ground that it contains such information must submit an application for withholding at the time of filing the information sought to be withheld. The application must be accompanied by an affidavit, executed by the owner of the information, which addresses with specificity certain considerations the Commission will consider in determining whether the information may be exempt. These considerations include whether the information is available in public sources and whether public disclosure of the information sought to be withheld is likely to cause substantial harm to the competitive position of the owner of the information.

If a claim for withholding is submitted by a company, the proposed rule would have required the supporting affidavit to be executed by an officer who had been specifically delegated the function of reviewing the information sought to be withheld and authorized to apply for its withholding on behalf of the company. Comments suggested that it would often be a hardship for a company officer to execute the affidavit. Moreover, some felt that the rule should allow for preparation of the affidavit by other than the owner of the information, such as a third party seeking a license who was allowed by the owner to use its confidential information in a license application. The final rule has been revised to provide that either an officer of the company or an "upper-level management official" may execute the affidavit, but it has not been amended to permit submission of affidavits by third parties. The rule requires the affidavit to be signed by the owner of the information so that the Commission will have proof that the information has been treated as confidential, has value, and the disclosure will be likely to cause substantial harm to the owner's competitive position.

The rule also has been amended to permit an owner to include trade secrets or confidential or privileged commercial information in the affidavit without subjecting such supporting information to the procedural requirements of the rule. To do otherwise could result in an unnecessary number of affidavits. Information clearly marked in the affidavit as proprietary to the owner will be withheld from disclosure in accordance with the provisions of 10 CFR Part 9 of the Commission's rules implementing the Freedom of Information Act. Should the owner not wish to reveal the supporting information to a third party who has been furnished the basic information and has incorporated it in a license application, the owner may submit the affidavit directly to the Commission, and it will be protected in accordance with the provisions of 10 CFR Part 9. If, after consideration of the facts provided in the supporting affidavit, the Commission determines that the document proposed for exemption from disclosure contains trade secrets or privileged or confidential commercial or financial information, it will then determine whether the right of the public to be fully apprised as to the bases for the effects of the proposed action outweighs the demonstrated concern for protection of a competitive position and whether the information should be withheld from public disclosure.

If a request for withholding is denied, paragraph (c) of § 2.790 provides that the Commission will notify the applicant for withholding of the denial and furnish a statement of reasons for its denial. The notice of denial will specify a time, not less than thirty days after the date of the notice, when the document will be placed in the Public Document Room. If, within the time specified in the notice, the applicant requests withdrawal of the document, it will not be placed in the Public Document Room and will be returned to the applicant. Information submitted in a rule making proceeding which subsequently forms the basis for the final rule will not be withheld, however, from public disclosure by the Commission and will not be returned to the applicant after denial of any application for withholding the information. Paragraph (c) has been revised to provide that information submitted to the Commission and found to be unnecessary or irrelevant to performance of the Commission's functions will be returned to the submitter.

Paragraph (d) of the proposed rule would have required the owner of information which the Commission determined should be withheld from public disclosure to submit a new affidavit at two year intervals which would justify the continued withholding of the information from public inspection. The Staff would have evaluated the claim for continued withholding of the information and determined whether to continue to exempt the information from disclosure or place the information in the Public Document Room. Many of those who responded to the Commission's request for comments objected to this feature of the proposed rule. They suggested that continued resubmission of affidavits would be costly and administratively burdensome.

The purpose of the proposed rejustification provision was to provide a mechanism for assuring that exempt commercial information which had formed a part of particular licensing actions by the Commission would eventually be made part of the public record. Other mechanisms, however, are available to assure the same result. Paragraph (b) of the final rule states, as do the Commission's present regulations in § 2.790, that withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned to inspect documents which have been withheld from public disclosure pursuant to that paragraph.

Under this provision, a party to a licensing or rule making proceeding who needs access to "proprietary information" may upon a proper showing of relevancy inspect such information under a protective order or upon signing of protective agreement. Moreover, the Commission may always on its own motion or that of a third party require the owner of information which has been previously deemed to be exempt from disclosure to provide a new affidavit justifying the continued confidential treatment of the information. The Commission's present regulations in 10 CFR Part 9 implementing the Freedom of Information Act would, for example, permit any member of the public to make a request for exempt information, and trade secret or other confidential business or financial

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[1] This was the second opportunity for public participation in the development of the rule. In November 1973 the Atomic Energy Commission published a notice in the FEDERAL REGISTER which stated that it was considering five alternatives regarding changes in its policy and rules for the protection and disclosure of proprietary information. Interested persons were invited to submit comments and suggestions with regard to the five alternatives or other alternatives (38 FR 31543).

information would be withheld from disclosure only upon a determination that the information remains proprietary to the owner at the time of the Freedom of Information Act request. For these and other reasons, therefore, the rejustification provision found in paragraph (d) of the proposed rule has been eliminated.

Paragraph (e) of the proposed rule has been relettered as paragraph (d). This provision previously stated that correspondence and reports to or from NRC which identify a licensee's or applicant's procedures for safeguarding licensed special nuclear material or detailed security measures for the physical protection of a licensed facility or plant in which licensed special nuclear material is used will be deemed to be commercial or financial information within the meaning of 10 CFR 9.5(a)(4) of the Commission's regulations implementing the Freedom of Information Act and will be subject to disclosure only in accordance with the provisions of 10 CFR Part 9. Paragraph (d) of the proposed rule has been revised to clarify that such documents will be withheld from disclosure if they identify security measures for the protection of a licensed facility or plant in which special nuclear material is "possessed" as well as "used."

One commenter suggested that the proposed rule be revised to exempt from disclosure all trade secrets and confidential or privileged commercial or financial information transmitted to the Commission by a foreign government or a foreign government agency. The Commission's regulations in 10 CFR 9.5(a)(4) would presently allow the confidentiality of such information to be protected. The Commission believes that to further subject foreign agencies or other foreign sources to the administrative requirements of § 2.790 could result in a reduction of information needed for important policy making and decision making functions. Accordingly, paragraph (d) of the proposed rule has been amended to provide that information submitted in confidence to the NRC by a foreign source is excluded from the application of § 2.790. Such information will be exempt from disclosure under 10 CFR 9.5(a)(4) of the Commission's regulations.

Paragraph (e) of the proposed rule has been relettered (d) in the final rule. It provides that a presiding officer or the Commission may, with reference to NRC records and documents made available pursuant to 10 CFR § 2.790, issue orders consistent with the provisions of 10 CFR § 2.790 and § 2.740(c).

In accordance with the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendment of Title 10, Chapter I, Code of Federal Regulations, Part 2 is published as a document subject to codification.

41 FR 15832
Published 4/15/76
Effective 5/17/76

Construction Permit or Operating License, Initial Treatment of Application

See Part 50 Statements of Consideration.

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41 FR 53328
Published 12/6/76
Effective 1/5/77

PART 2—RULES OF PRACTICE

Special Procedures Applicable to Adjudicatory Proceedings Involving Restricted Data or Other National Security Information

Section 181 of the Atomic Energy Act of 1954, as amended, provides in part that in the case of Nuclear Regulatory Commission ("Commission") proceedings which involve Restricted Data or defense information, the Commission shall provide by regulation for such parallel procedures as will effectively safeguard and prevent disclosure of Restricted Data or defense information to unauthorized persons with minimum impairment of the procedural rights which would be available if Restricted Data or defense information were not involved.

Commission regulations which implement the above cited portion of section 181 in the case of proceedings involving Restricted Data are set forth in 10 CFR Part 2, Subpart I. Subpart I as it presently appears in 10 CFR Part 2 has remained essentially unchanged for the past fourteen years, and no occasion has yet arisen where Subpart I was required to be fully applied to any licensing proceeding. Nevertheless the occasion may arise in the future when classified information may become included in Commisison proceedings, and the Commission has reviewed Subpart I with a view toward updating the provisions set forth therein. The revised Subpart I set forth below is essentially the same as the old Subpart, except that (1) National Security information has been included along with Restricted Data, (2) The Subpart has been clarified so as to clearly apply to licensing proceedings required by law to be determined on the record after opportunity for an adjudicatory hearing, (3) The Commission itself (rather than the presiding officer) would act on requests for access to classified information where the information originated in another Government agency, (4) Access would not be granted to classified information which originated in another government agency if the originating agency objects in writing to granting of access, and (5) A party requesting access to classified information must execute an agreement not to disclose the information without authority.

In promulgating these amendments the Commission believes it desirable to emphasize that while parties to affected proceedings have an obligation to avoid introducing classified information where it is practicable to do so, this obligation in no way detracts from the concomitant obligation of parties to come forward with relevant and material documents whether or not classified.

As was true for the original Subpart I, the revised Subpart I applies only to classified information in the possession of or under the control of the Commission. It does not apply to discovery of classified information in the possession of or under the control of applicants for Commission licenses or permits or other persons or agencies. Requests for classified information in the possession or control of applicants or other persons or agencies would be governed by 10 CFR 2.740–2.742, and the Commission expects that any significant questions regarding discovery of such classified information in Commission proceedings would be certified to the Atomic Safety and Licensing Appeal Board and Commission for decision. 10 CFR 2.718(i), 2.785(d).

Since the amendments which follow relate to rules of agency procedure and practice, notice of proposed rule making and public procedure thereon are not required by section 553 of title 5 of the United States Code. Accordingly, pursuant to section 181 of the Atomic Energy Act of 1954, as amended, section 201 of the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendment to title 10 of the Code of Federal Regulations, Part 2 is published as a document subject to codification.

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42 FR 12875
Published 3/7/77
Effective 3/12/77

Rules Governing Public Attendance at Meetings of the Nuclear Regulatory Commission

See Part 9 Statements of Consideration.

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42 FR 22128
Published 5/2/77
Effective 6/1/77

PART 2—RULES OF PRACTICE

Commission Review of Appeal Board Decisions and Procedure for Request for Stays

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Commission is amending its rules of practice to provide a procedure for parties to petition the Commission for a discretionary review of a decision or action of the Atomic Safety and Licensing Appeal Board. The Commission is also providing a procedure for parties to apply for stays of the decisions or actions of both presiding officers and the Atomic Safety and Licensing Appeal Board. Based on its experience, the Commission is issuing these rules because it believes that they will be of benefit to parties to proceedings.

EFFECTIVE DATE: June 1, 1977.

FOR FURTHER INFORMATION CONTACT:

Martin G. Malsch, Director and Chief Counsel, Regulations Division, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (202–492–7203).

SUPPLEMENTARY INFORMATION: On November 13, 1976, the Commission published for comment two new proposed sections to 10 CFR Part 2. The first of the new sections, § 2.786, would provide a procedure for Commission review of decisions and actions of an Atomic Safety and Licensing Appeal Board. The second new section, § 2.788, would provide a procedure for requesting stays of decisions and actions of presiding officers and Atomic Safety and Licensing Appeal Boards pending review.

It is anticipated that the use of petitions for discretionary review will increase participation in the Commission's decision making process and provide the Commission with focused views on the validity and impact of Appeal Board decisions. It is hoped that the new procedures will not impose an expensive and time consuming burden on parties to licensing proceedings and ultimately on the public.

The rules of practice for requesting stays now provide a formal procedure for seeking that extraordinary relief. As with the procedure for discretionary review, the Commission intends to follow closely the application of these rules in practice with a view to making whatever changes are necessary to reduce unnecessary burdens and prevent abuse or unwarranted harassment of parties by their misuse.

Comments. Nine letters of comment were received from members of the public with respect to these two proposed sections. All of the comments favored the promulgation of regulations providing for discretionary review and for stays of decisions. Several of the commentors, however, had detailed remarks on the procedures and offered detailed drafting changes to the proposed regulations. The comments and their resolutions are as follows:

(1) Two comments were addressed to § 2.786(b)(1). It was noted that the paragraph allowed for a petition with respect to an important question of law or policy, but did not allow for a petition with respect to factual matters. It was pointed out that the rule in § 2.786(b)(4)(ii) implied a review of a question of fact when an Atomic Safety and Licensing Board and an Appeal Board differed in their view of a factual issue. The comment is well taken, and § 2.786(b)(1) has been amended by the addition of the word "fact" before the phrase "law or policy." The second comment questioned the reasonableness of excluding petitions concerning interlocutory matters. The Commission has decided not to change the section in this regard. The review procedure under § 2.786(b) is intended to provide a limited review only of decisions and actions by Appeal Boards that would otherwise be final.

(2) With respect to proposed § 2.786(b)(2)(ii), it was pointed out that the final phrase "if they were not, why not" appeared to be in conflict with the language of § 2.786(b)(4)(iii) that petitions would not be granted to the extent they relied upon matters that could have been but were not raised before the Appeal Board. Asking for the petitioner to explain why matters were not raised appeared to some commentors to conflict with the latter provision. The point of confusion is recognized, and § 2.786(b)(2)(ii) has been amended so that it is clear that the explanatory statement required in the petition should address why matters not raised before the Appeal Board could not have been raised there. If the matter could not have been raised before the Appeal Board, then the constraint in § 2.786(b)(4)(iii) does not apply. A similar change has been made to § 2.788(b)(3).

(3) Several commentors questioned the wisdom of not allowing answers in support of a petition. The difficulty with such answers is that they could raise new arguments without giving other parties an opportunity to respond since, for purposes of efficiency, the Commission does not desire further pleadings after answers are filed. Accordingly, all those who support review should petition under § 2.786(b)(1) within 15 days after service of the Appeal Board decision. This does not mean that duplicative petitions must be filed. Parties can communicate informally prior to filing, and one petition can incorporate by reference the substance of another.

(4) Several commentors questioned whether the limitations on review in § 2.786(b)(4)(ii), (iii) and (iv) should be as inflexible as they appear. It was suggested that in each of the three limiting subparagraphs the word "ordinarily" should be inserted to indicate that in each of those areas the Commission would also act in its discretion. The Commission in this respect intends a set of strict rules in order to retain the concept of a limited review. Accordingly, it prefers, at this time, not to exercise its discretion within the enumerated areas of constraint in § 2.768(b)(4)(ii), (iii) and (iv). The word "ordinarily" is retained in § 2.786(b)(4)(i) since that paragraph concerns more fundamental matters of Commission concern in which a broader degree of discretion is appropriate.

(5) Other comments on § 2.786(b)(4) suggested including important antitrust considerations and important procedural questions as reviewable matters under § 2.786(b)(4)(i). The Commission accepts these comments. The paragraph has been amended accordingly. In addition, one commentor suggested allowing a generalized right to request review as to questions of law in § 2.786(b)(4). The Commission believes, however, that at this time it is preferable procedure to limit its review of questions of law to those involving significant environmental, public health and safety, common defense and security, antitrust or procedural issues, or those questions of law which raise important questions of public policy. Accordingly, no change has been made in this regard.

(6) Commentors also question whether it was appropriate in § 2.786(b)(4)(ii) to preclude Commission review when both the Licensing Board and Appeal Board came to the same factual determinations when the factual determination by both was erroneous. The Commission believes that as to factual matters, two levels of decision within the agency are enough, and that there is no need for a third factual review by the Commission itself.

(7) Further question was raised by a commentor as to whether the constraint in § 2.786(b)(4)(iii) applied to issues raised sua sponte by the Appeal Board itself. The Commission believes that if the Appeal Board raises an issue sua sponte then that is an issue "raised before" the Appeal Board. In order to resolve the ambiguity an appropriate change is made in § 2.786(b)(4)(iii).

(8) In addition to the foregoing, a new paragraph (iv) has been added to § 2.786(b)(4). The new paragraph is in response to comments raising the question of the possibility of duplicate or alternative review requests, one by a motion for reconsideration filed with the Appeal Board and one by a petition for review filed with the Commission. The new paragraph states that a petition for review will not be granted as to issues raised before an Atomic Safety and Licensing Appeal Board on a pending motion for reconsideration. When a reconsideration motion is disposed of, a party may then seek further review by filing a petition for review under § 2.786(b)(1). Seeking reconsideration is not, however, a precondition for a § 2.786(b)(1) petition.

(9) Commentors also raised the question as to whether the proposed rule left open questions of finality of Commission decisions and orders. It is the considered judgment of the Commission that no changes are necessary in § 2.786(b)(5) to meet questions of finality. In the Commission's view, a decision is clearly final under the rule 20 days after filing the petition for review if the Commission has not acted, and, if the Commission grants the petition, Commission action would be final after it has reviewed the matter and issued its decision.

(10) With respect to § 2.786(b)(6) one commentor suggested that participation should not be limited to parties designated by the Commission, but that others should be allowed to file appropriate pleadings and briefs. Because the Commission may desire to limit review to issues involving only certain parties, it does not accept this suggestion.

(11) A comment raised the question as to the necessity of § 2.786(b)(7), noting that acceptance of petitions for reconsideration should be a matter of Commission discretion and need not be stated in a rule. The Commission believes that the provision that it will not accept petitions for reconsideration of Commission decisions granting or denying review in whole or part serves to put parties on notice not to file petitions for reconsideration. The Commission believes that at some point there must be an end to litigation before it. The provision also underscores the finality of denial by silence after 20 days.

With respect to proposed § 2.788, "Stays of Decisions of Presiding Officers and Atomic Safety and Licensing Appeal Boards Pending Review," several commentors commented upon the confusion engendered by including a parenthetical provision allowing an application for a stay of a decision or action denying or granting a stay within the provision for an application for a stay with respect to a decision or action on substantive issues. In order to resolve the apparent confusion the parenthetical expression is deleted from § 2.788(a) and a new paragraph (h) has been added to the section. The new paragraph provides that any party to the proceeding may file an application for a stay of the effectiveness of a decision or action denying or granting a stay. With respect to the decision or action of a presiding officer the new paragraph notes that the application shall be filed with the Atomic Safety and Licensing Appeal Board and with respect to the decision or action of an Atomic Safety and Licensing Appeal Board that the application shall be filed with the Commission. This aspect of the new paragraph differs from the general rule in § 2.788(f) as to where an application for a stay should be filed in other circumstances. The Commission agrees with commentors that it does not appear appropriate or necessary with respect to a request for a stay of a decision or action on a stay to go back again to the same body that either granted or denied the stay in the first instance. The Commission emphasizes, however, that this variation applies only to the unique situation of filing an application for a stay with respect to a decision or action that in itself denied or granted an application for a stay.

Other comments on § 2.788 were of a relatively minor nature and involved primarily drafting problems.

(1) A comment noted that it would be appropriate in § 2.788(b)(4) that references to the record with respect to factual disputes would be appropriate. The Commission agrees and has changed the wording of that paragraph accordingly.

(2) A commentor commented that § 2.788(c) was confusing as to the method for filing the application. The commentor apparently read the section as requiring that the procedure for serving shall be the same as the procedure for filing. This was not the intention of the Commission. The Commission intended that service shall be by the same method of communication as used for filing, that is, if the application is filed by telegram it should be served by telegram. Appropriate words have been added to clarify the intention.

(3) Several commentors noted that §§ 2.788(d) and 2.788(g) had different time periods and different rules for the filing of answers to applications for a stay. In order to resolve the apparent conflict, the Commission has decided to delete in its entirety § 2.788(g) on the ground that it is redundant and unnecessary if other appropriate drafting changes are made in § 2.788(d). These other changes are also responsive to comments. They include, amending § 2.788(d) to change the period of time for filing an answer to an application from 10 days to 7 days. Appropriate drafting changes are also made to indicate clearly that answers both supporting or opposing the granting of a stay may be filed within the time period allowed. Here, unlike the situation with petitions for review, answers in support may be unavoidable since time pressures could prevent the informal communications that enable one filing to incorporate another. It is further clarified that no further replies will be entertained on the ground that replies to answers are not seen as necessary at this stage since the issues should already be precisely defined. The last sentence of § 2.788(d) is amended to conform with the changes made in § 2.788(c) as to the use of like communications methods for both service and filing.

(4) Commentors also raise the question of whether it was appropriate to codify the criteria to be considered in granting or denying a request for a stay. The Commission is of the opinion that it is appropriate to codify these criteria in the regulations on the ground that the codification will assist the parties in framing their applications for and their answers to requests for stays. One commentor suggested removal of the word "highly" in the first criterion. That criterion, like the others, is based on *Virginia Petroleum Jobber's Association* v. *FPC*, 259 F. 2d 921, 925 (D.C. Cir. 1958), and represents a standard that has been previously applied by the Commission. See *In the Matter of Petition of Natural Resources Defense Council*, NRCI-76/2 at 78 (February 12, 1976). The precise phrasing of the first *Virginia Petroleum* criterion is whether the moving party has made a "strong showing that it is likely to prevail on the merits of its appeal." That phrasing has been substituted for the previous version of the first criterion.

(5) A commentor suggested that § 2.788(f) be revised to require that the request for a stay be made to the deciding body above the body that issued the decision as to which the stay is requested. That is, with respect to an Atomic Safety and Licensing Board decision the stay would be requested from the Appeal Board. With respect to an Appeal Board decision the request for a stay would be made to the Commission. The Commission does not believe it appropriate for this procedure to be followed with respect to requests for stays of decisions or actions on substantive issues. Unlike the case addressed in new § 2.788(h) dealing with a stay of a stay, the Commission believes it more desirable that the Appeal Board review in the first instance the request of a stay of its decisions or actions on substantive issues.

(6) Former § 2.788(h) has been renumbered as § 2.788(g), and has been redrafted as suggested by a commentor to provide greater clarity and precision as to the extraordinary request for a temporary stay to preserve the status quo. Also, a provision has been added to the effect that a party applying orally must make all reasonable effort to inform other parties orally of the application for a stay to preserve the status quo prior to the filing of answers.

(7) A request was made to define "decision or action" as used in both §§ 2.786 and 2.788. The Commission does not believe it is necessary to do so at this time. If experience shows that the phrase leads to unnecessary applications for review or a stay, the Commission can amend the rule to further limit its scope.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to 10 CFR Part 2 are published as a document subject to codification, to be effective on June 1, 1977.

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42 FR 22882
Published 5/5/77
Effective 6/6/77

Early Site Reviews and Limited Work Authorizations

See Part 50 Statements of Consideration.

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42 FR 28891
Published 6/6/77
Effective 7/6/77; §§ 21.6, 21.21(a), and 21.51 effective 1/6/78
(7/6/77 effective date extended to 8/10/77)

Reports to the Commission Concerning Defects and Noncompliance

See Part 21 Statements of Consideration.

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42 FR 36239
Published 7/14/77
Effective 8/15/77

PART 2—RULES OF PRACTICE

Petitions for Review of Director's Denial of Enforcement Requests

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: This amendment to the Commission's rules of practice provides procedures under which the Commission may, on its own motion, review a Director's decision denying a request to institute enforcement proceedings in order to determine whether the Director has abused his discretion. The amendment also makes clear that the Commission will not entertain petitions for Commission review of a Director's denial of enforcement requests. Prior to this amendment, the Commission's rules contained no provisions respecting review of such denials although the Commission has on several occasions conducted such reviews. The amendment sets out procedures which will give the Commission an opportunity to determine whether or not to institute a review of a Director's decision on its own motion.

EFFECTIVE DATE: August 15, 1977.

FOR FURTHER INFORMATION CONTACT:

Martin G. Malsch, Office of the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, phone 301-492-7203.

SUPPLEMENTARY INFORMATION: Under 10 CFR 2.206 of the Commission's rules of practice, any person may request that the Directors of the Offices of Nuclear Reactor Regulation, Nuclear Material Safety and Safeguards, or Inspection and Enforcement institute a proceeding to modify, suspend, or revoke a license or take other enforcement action. When such requests are received, the affected licensee or permittee is notified, and a notice of receipt of the request is published in the FEDERAL REGISTER. This process is followed except for those occasional requests that so obviously lack merit that a more abbreviated procedure may appropriately be followed.

If the request is granted and the licensee or permittee protests, the resulting contested proceeding will be heard by an Atomic Safety and Licensing Board or Administrative Law Judge and will eventually be subject to Atomic Safety and Licensing Appeal Board and Commission review. If, on the other hand, the request is denied, the requester is always provided by the Office Director with a written detailed statement explaining the reasons for denial. The Commission's rules make no provision for review of Director's decisions. However, in three instances the Commission has in fact reviewed denials of enforcement requests. "Licensees Authorized to Possess or Transport Strategic Quantities of Special Nuclear Materials," 5 NRC 16 (1977), "Consolidated Edison Company of New York, Inc. (Indian Point, Units 1, 2 and 3)," 2 NRC 173 (1975), "Consumers Power Company (Midland Plant, Units 1 and 2)," 6 AEC 1082 (1973). Requests for Commission review of the Director's denial of enforcement action regarding the Bailly plant are presently before the Commission.

The Commission has decided that further petitions seeking Commission review of Director's denials under 10 CFR 2.206 will not be entertained. The Commission will continue to receive copies of Director's decisions under 10 CFR 2.206 and retains the power to review Director's denials sua sponte, in whole or part. The amendment to 10 CFR 2.206 set forth below is intended to codify this Commission decision. Under the amendment, any sua sponte review by the Commission would be conducted within 20 days of the Director's denial, unless the time is extended by the Commission. This sua sponte review power does not limit in any way either the Commission's supervisory power over delegated Staff authority under 10 CFR 2.206, or the Commission's power to consult with the Staff on a formal or informal basis regarding initiation of proceedings under 10 CFR 2.206.

Because this amendment relates solely to matters of agency procedure, notice of proposed rulemaking and public procedure thereon are not required by section 553 of Title 5 of the United States Code.

Accordingly, pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendment to Title 10, Chapter I, Code of Federal Regulations, Part 2, is published as a document subject to codification.

43 FR 7209
Published 2/21/78
Effective 2/21/78

Distribution of Environmental Impact Statements

See Part 51 Proposed Rule Making.

43 FR 6915
Published 2/17/78
Effective 5/3/78

Export and Import of Nuclear Facilities and Materials

See Part 110 Statements of Consideration.

43 FR 16446
Published 4/19/78
Effective 4/19/78

PART 2—RULES OF PRACTICE

Orders to Show Cause

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its "Rules of Practice" to provide that the Director, Office of Administration may institute a proceeding to modify, suspend, or revoke a license or for such other action as may be proper by serving on the licensee an order to show cause.

DATE: This amendment will be effective on April 19, 1978.

FOR FURTHER INFORMATION CONTACT:

Mr. W. O. Miller, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, 301-492-7225.

SUPPLEMENTARY INFORMATION: The amendment of § 2.202 of 10 CFR Part 2 set forth below adds the Director, Office of Administration to the Officials specified therein who may institute a proceeding to modify, suspend, or revoke a license or for such other action as may be proper by serving on the licensee an order to show cause.

Because this amendment relates solely to matters of agency management and procedure, notice of proposed rule making and public procedure thereon are not required by section 553 of title 5 of the United States Code, and the amendment may be made effective April 19, 1978.

Accordingly, pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendment to title 10, Chapter I, Code of Federal Regulations, Part 2, is published as a document subject to codification.

43 FR 17798
Published 4/26/78
Effective 5/26/78

PART 2—RULES OF PRACTICE

PART 8—INTERPRETATIONS

Miscellaneous Amendments

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending certain sections of its "Rules of Practice" to facilitate public participation in its facility license application review and hearing process, to improve coordination with States, counties, and municipalities, and to make certain other improvements.

DATE: This rule becomes effective on May 26, 1978.

FOR FURTHER INFORMATION CONTACT:

Mr. Marc R. Staenberg, Office of the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, 301-492-7437.

SUPPLEMENTARY INFORMATION: In 1972, the Atomic Energy Commission (now the Nuclear Regulatory Commission)[1] undertook a comprehensive and in-depth examination of its Rules of Practice with a view toward expediting the decision process. As a result, comprehensive amendments to the Rules of Practice in 10 CFR Part 2 were proposed in May 1972 (37 FR 9331) and, after consideration of public comments, effective amendments were published in July 1972 (37 FR 15127).

Experience under the restructured rules suggested the desirability of certain additional improvements. Therefore, on May 2, 1977, the Commission published in the FEDERAL REGISTER (42 FR 22168) for comment proposed amendments to 10 CFR Part 2 which would facilitate public participation in its facility license application review and hearing process, improve coordination with States, counties, and municipalities, and establish more reasonable time limits in the review and hearing process.

Seventeen comments were received on the proposed rules—twelve from representatives of the nuclear power industry, two from environmentally concerned citizen groups, one from a state government, and two from individual citizens. Though the comments offered support for some of the proposed changes and no objections to certain others, there was some general concern expressed by representatives of the nuclear power industry that the extension of certain time periods in the license review and hearing process would result in a substantially lengthened hearing process. The Commission is committed to developing a hearing process which will produce decisions in a timely fashion. Therefore, the Commission has carefully considered the objections to the proposed rule change in light of current practices in the review and hearing process. It is apparent from current practice that some of the time limits presently set out in the Rules of Practice have proven to be too short and unrealistic. As a result, a routine practice of requests and grants of extensions of time has developed. The Commission takes this opportunity to set forth more reasonable time limits for certain portions of the review and hearing process, but wishes to indicate that it expects that these new time limits will be more closely adhered to, and that there will be less reason for extensions of time in such proceedings. The final rule differs somewhat from the proposed rule in this area. Rather than attempt to modify the interplay between § 2.710 and other timing provisions, the final rule (1) makes discrete changes to time limits in specific sections to provide a slight increase in the time for responses by the Staff and by the other parties, (2) removes the somewhat confusing sentence in § 2.710 regarding exclusion of Saturdays, Sundays and holidays in calculating time limits in certain circumstances, so that Saturdays, Sundays and holidays are now always included unless specifically excluded by the presiding officer and (3) revokes the General Counsel's interpretation of § 2.710 (found at 10 CFR § 8.3) regarding inclusion of Saturdays, Sundays and holidays in calculating time limits. The effects of these changes are to increase slightly the time limits and to simplify the calculation of time limits by allowing for straight calculation of days including Saturdays, Sundays and holidays. It is the Commission's expectation that these changes will lead to a more simplified hearing and prehearing process without any significant delays.

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[1] Pursuant to the Energy Reorganization Act of 1974, as amended, the Atomic Energy Commission was abolished and the Nuclear Regulatory Commission (NRC) assumed the licensing and related regulatory functions of the AEC.

The specific amendments are further described below.

1. *Petitions to intervene.* The present rule, § 2.714, requires that petitions for leave to intervene include both the petitioner's contentions and an affidavit which sets forth with particularity how petitioner's interest may be affected and the bases for petitioner's contentions in the proceeding. Current practice has generally provided 30 days between the date a notice of hearing or notice of proposed action on an application for a nuclear power plant construction permit or operating license is published in the FEDERAL REGISTER and the last date for filing of timely petitions for leave to intervene. In contrast, the time generally required for complete review of the application for a nuclear power plant construction permit or operating license is over one year. Any contested hearings on such applications would likely commence more than six months after the expiration of the time for receipt of timely intervention petitions.

Experience has indicated that 30 days is often insufficient for potential petitioners to frame and support adequate contentions. It has become common practice for parties and petitioners in nuclear power plant licensing proceedings to discuss informally the framing of contentions until just before the special prehearing conference which is held some months or more after expiration of the 30 day period for timely petitions pursuant to § 2.751a. During this period the contentions are frequently revised based on the discussions among the parties and petitioners. Often the petitioners and parties will be able to present the presiding atomic safety and licensing board with an agreed upon set of contentions at the special prehearing conference. This practice reduces unnecessary controversy and litigation and should be encouraged. Accordingly, the rules are amended to permit the filing of contentions until shortly before the special prehearing conference. In this connection, § 2.751a, which generally provides for a special prehearing conference within 60 days after the notice of hearing, is amended to generally provide for a special prehearing conference within 90 days of the notice of hearing. This amendment more closely conforms with present practice. Timely petitions to intervene which address the petitioners' interest in the proceeding will still be filed within the initial 30 day period. At the same time, adequate time for discovery and preparation for hearing should remain, so that the time required for completion of the formal hearing process should be the same. This represents no change from the proposed rule.

At present, § 2.714(c), provides that answers to a petition for leave to intervene must be filed by a party within 5 days afer the petition for leave to intervene is filed. The Staff is given 10 days to answer. Experience has indicated that the present time limits are too short. As proposed, the time allowed to answer petitions is increased to 10 days for parties and to 15 days for the Staff. As a consequence of the interplay between these amendments and the amendments to § 2.710, described above, only a few days additional time will in fact result.

As proposed, the requirement that an affidavit accompany petitions to intervene is also abolished. Experience has shown that such affidavits do not serve a useful purpose at this early stage in licensing proceedings. Furthermore, the seriousness and accuracy of petitioners' contentions are adequately ensured by the requirement that all testimony at the hearing must be given under oath.

2. *Late filing of petitions and contentions.* At present, § 2.714 provides that late filed petitions will not be admitted absent a determination that petitioner has made a substantial showing of good cause and with reference to a balancing of specified factors. There is no provision in § 2.714 which specifically addresses the matter of amending or expanding contentions after a petitioner has been admitted as a party. Yet contentions are frequently expanded or amended because of new information which comes to light after petitioners have been admitted, such as information in the Commission Staff's safety evaluation or environmental impact statements.

The Commission believes that § 2.714 should be amended in the interest of clarifying the requirements in regard to both late filings of petitions and amending, expanding, and deleting contentions. First, § 2.714 is amended to outline clearly the factors which need to be considered and balanced before the presiding officer passes upon the admissibility of late filings. In essence, the amendment codifies the Commission's decision *In the Matter of Nuclear Fuel Services, Inc., and New York State Atomic and Space Development Authority* (1 NRC 273), which makes clear that the reason for the untimely filing is one factor to be balanced along with others in determining whether a late filing will be admitted. Second, § 2.714 is revised to specifically provide that late filed contentions (a contention or amended contention which is filed after 15 days prior to the special prehearing conference, or where there is no special prehearing conference, which is filed after 15 days prior to the first prehearing conference) will be considered for admission under the clarified criteria set forth in subparagraph (a)(1). Third, revised § 2.714 is intended to make clear that late filed contentions must meet the same requirements as timely filed contentions. That is, a proposed contention must be set forth with particularity and with the appropriate factual basis. Finally, this section has been generally reorganized to make the language more clear and to incorporate the present practice of granting intervention based upon adequate interest and at least one adequate contention. These changes represent no change from those in the proposed rule.

3. *Time for staff answers and mailings.* The proposed rule would have amended § 2.710 (computation of time) to adjust the interplay between § 2.710 and other sections of the rule which purported to provide the Staff with additional time. Based upon comments and further consideration, it is believed that the better course is to amend the individual sections of the rule and amend § 2.710 to provide for straight calculation of time and thereby abolish the exclusion of intermediate Saturdays, Sundays and holidays.

Therefore, the final rule deletes the sentence in § 2.710 and footnote reference to § 8.3, and revokes the General Counsel interpretation of § 2.710 contained in § 8.3, which indicated in what circumstances Saturdays, Sundays and holidays were to be excluded from the computation of days. Instead, weekends and holidays will henceforth be included in the computation of time unless specifically ordered otherwise by the presiding officer.

In this regard, the time limits in the individual sections of the rule (§§ 2.706, 2.714(c), 2.730(c), 2.740(f), 2.740a(f), 2.743(b), 2.749(a), 2.754, 2.762(a), 2.771(b) and 2.788) have been increased to take account of this new manner of computation as well as to provide some small additional time, in fact, to parties and Staff.

As proposed, the final rule increases the time allowed for service by mail from 3 to 5 days.

4. *Expanded participation: Limited appearances at prehearings, interested counties and cities, and "Amicus" participation.* Section 2.715 sets forth the ground rules for limited appearances at NRC proceedings and for participation by interested States without the necessity for their being admitted as a party under § 2.714. This form of participation by members of the public and the States has been a welcome and valuable part of the Commission's licensing proceedings.

(a) At present, § 2.715(a) provides for limited appearances, at the presiding officer's discretion, during the course of a proceeding. This discretion has been exercised to permit limited appearances at a hearing but has generally excluded such appearances at prehearing conferences. Since prehearing conferences often precede the hearing by several months, members of the public attending prehearing conferences are sometimes understandably disappointed when they learn that their limited appearance must be postponed until some uncertain date in the future. Experience indicates that members of the public are often interested in making their limited appearances early in the licensing process. Therefore, as proposed, § 2.715(a) is amended to clarify that limited appearances may be allowed at prehearing conferences as well as at the hearing.

(b) Section 2.715(c) of the Commission's Rules of Practice permit interested States to participate in NRC licensing proceedings without taking a position with respect to the issues. Pursuant to section 161 of the Atomic Energy Act, which grants broad discretionary authority to the Commission to obtain information, make investigations or hold hearings as it deems necessary, this type of cooperation could be extended to other units of government which also have an interest in the licensing proceeding. Therefore, § 2.715(c) is expanded to include interested cities, counties, and agencies thereof. In addition, § 2.715(c) is amended to specifically provide that such interested States, counties, cities, and agencies thereof may, in addition to participation at the hearing, file proposed findings of fact and conclusions of law pursuant to § 2.754, file exceptions (appeals) pursuant to § 2.762 and petition for review by the Commission pursuant to § 2.786. It is, however, further provided that the presiding officer may require such participants to indicate, in advance of the hearing, the subject matters on which they desire to participate. These amendments conform to present practice and represent no change from the proposed rule.

(c) At present, there is no specific provision in Part 2 for participation in appeals before the Atomic Safety and Licensing Appeal Board or Commission by a person in an "amicus" capacity on particular legal or factual issues. Although discretion already rests with the Commission or Appeal Board to permit such "amicus" participation, a new paragraph (d) is added to § 2.715 to set forth specifically the guidelines for such participation. It is envisioned that a person who is not a party and who seeks to so participate will move for permission to file a brief in support of an existing party. Oral argument will be granted to such persons at the discretion of the Appeal Board or the Commission. This provision is as proposed.

5. *Consolidated and joint hearings with States.* At present, the rules (§§ 2.402 and 2.716) provide that the Commission may consolidate for hearing two or more proceedings if it finds that consolidation is desirable. There appears to be no good reason why such authority should only rest with the Commission or Atomic Safety and Licensing Appeal Board. Therefore, as proposed, the authority to consolidate two or more proceedings is hereby extended to Atomic Safety and Licensing Boards.

Also, § 2.716 is amended to provide specific authority to hold joint hearings with States and/or other Federal agencies on matters of concurrent jurisdiction provided that the Commission's Rules of Practice are not waived. Joint hearings promise to minimize duplication in the reviews by the Commission, State and/or Federal agencies, and improve State and interagency coordination. Whether joint hearings should be held will be determined on a case-by-case basis.

These changes allowing Atomic Safety and Licensing Boards to consolidate hearings or to hold joint hearings with other agencies are expected to be used to avoid costly and time-consuming duplication of effort. Consolidation would only be proper when such action is separately approved by each of the affected Licensing Boards. Joint hearings would similarly be appropriate only where approved by the Board and each of the State or other Federal agencies involved.

6. *Earlier filing of written testimony.* At present, § 2.743(b) provides that written testimony must be served on each other party at least 5 days in advance of the session of the hearing at which the testimony is to be presented. In light of experience which suggests that 5 days is often too short for review of testimony, the time for filing testimony is amended to 15 days in advance of the hearing at which it will be presented. This amendment also responds to a petition for rule making filed with the Commission by Forelaws on Board and the Coalition for Safe Power (Docket No. PRM-2-3). The petitioners requested that § 2.743(b) be changed to provide that written testimony be filed "at least thirty (30) days in advance of the hearing * * * unless otherwise agreed upon by all parties and the presiding officer." Notice of receipt of the petitions and a request for public comment was published on September 7, 1976 (41 FR 37605). One comment, opposed to the petition, was received.

The Commission has given consideration to the petition, comment, and its own experience in changing the time for filing testimony from 5 days to 15 days in advance of the hearing. It was necessary, in reaching this position, to balance the needs of parties to have adequate time to consider written testimony and prepare for the hearing, with the Commission's goal of avoiding unwarranted delays. The Commission believes that the 30 day period suggested by petitioners would be unnecessarily long in the majority of cases. At the same time, the rules allow the presiding officer flexibility to impose a greater than 15 day period for advance filing of written testimony—including 30 days—in complex cases. This represents no change from the proposed rule.

7. *Summary disposition.* (a) Motions for summary disposition have proved to be a very valuable tool for disposing of issues which have little arguable merit. However, § 2.749 does not provide adequate time limits for such motions. At present, motions for summary disposition must be filed 10 days before the time fixed for the hearing and answers must be filed 2 days before the date of hearing.

Usually such motions are filed well before these dates and contain an extensive factual presentation. Thus, these filing times do not give parties a reasonable period of time in which to respond nor the presiding officer adequate time to consider the response.

Therefore, as proposed, § 2.749 is amended to require that (1) motions for summary disposition be filed at least 45 days before the time fixed for evidentiary hearings and (2) answers be filed within 20 days after service of the motion, unless other time limits are specified by the presiding officer. It is expected that this will facilitate responses to motions for summary disposition and consideration of the motions and answers by presiding boards. It is hoped that with adequate time, last minute delays in commencement of hearings caused by such motions may be avoided.

(b) Section 2.749 is also amended to broaden its applicability. At present, § 2.749 states that, "any party to an *initial licensing proceeding* may . . . move . . . for decision . . ." There appears to be no reason to limit the use of summary disposition solely to initial licensing actions. By deleting the reference to "initial licensing", summary disposition may be utilized in other of the Commission's adjudicatory proceedings, such as enforcement proceedings.

8. *Findings and conclusions.* Review of § 2.754, which sets forth the time requirements for the filing of findings of fact and conclusions of law, revealed an apparent inconsistency between the general language of paragraph (a) and the more specific provision of paragraph (b). In addition, experience suggests that the time limits established in paragraph (b) are too short.

Therefore, as proposed, §§ 2.754 (a) and (b) are revised to clarify the time requirements under which parties must file, unless otherwise provided by the presiding officer. In addition, the time allowed parties, pursuant to subparagraphs (a)(1) and (a)(2), to file their findings and conclusions is increased. It is expected that this increased time will allow sufficient time for the filing of findings and conclusions in ordinary cases.

9. *Application of time limits to decisions on limited work authorizations.* Section 2.760(a) is amended to clarify that final action is considered to be taken 45 days after a decision on a limited work authorization. This amendment simply includes limited work authorizations among those licensing matters that become final 45 days after the initial decision by the presiding officer.

10. *Additional briefing time on exceptions to initial decisions.* (a) At present, § 2.762(a) provides that within 7 days after service of an initial decision, any party may take an appeal to the Commission by the filing of exceptions to that decision or designated portions thereof. Section 2.762(a) further provides that briefs in support of exceptions must be filed within 15 days (20 days for the Staff) after the filing of exceptions. Experience has shown that these time periods are often too short. The result has been that parties do not have adequate opportunity to thoroughly consider the initial decision and brief exceptions.

Therefore, as proposed, § 2.762(a) is

amended to provide that exceptions, if any, must be filed within 10 days after service of the initial decision and that briefs in support of exceptions must be filed within 30 days (40 days for the Staff) after the filing of exceptions.

(b) Section 2.762(b) likewise provided 15 days and 20 days to parties and staff, respectively, when such party wished to file a brief in support of or opposition to a brief filed pursuant to § 2.762(a). In order to maintain consistency between § 2.762 (a) and (b), the final rule reflects that the time allowed for briefs filed pursuant to § 2.762(b) shall be 30 days for parties and 40 days for the staff. It is hoped that these changes will offer sufficient time for improved briefs and less reason for filing requests for additional time.

In promulgating these amendments, the Commission recognizes both an obligation to the segment of the public participating in the Commission's licensing process to provide an adequate forum for the consideration and resolution of their concerns, and a responsibility to the general public to arrive at sound licensing decisions in a timely fashion. The Commission expects that these amendments will improve the hearing process without causing significant delays in reaching sound licensing decisions.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of Title 5 of the United States Code, notice is hereby given that the following amendments of 10 CFR Part 2 are published as a document subject to codification. Since the new amendments described in paragraphs 3, 7(b), 9 and 10(b) of the preamble constitute rules of agency procedure and practice, notice of proposed rulemaking and public procedure thereon are not required by section 553 of Title 5 of the United States Code.

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43 FR 22345
Published 5/25/78
Effective 5/25/78

PART 2—RULES OF PRACTICE

Authority of Secretary to Rule on Procedural Matters

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Commission is amending its regulation governing its policy on granting of extensions of time for Commission review of certain decisions and actions by expanding the authority of the Secretary of the Commission to grant such extensions.

EFFECTIVE DATE: May 25, 1978.

FOR FURTHER INFORMATION CONTACT:

Stephen S. Ostrach, 202-254-8017.

SUPPLEMENTARY INFORMATION: None.

Because this amendment relates solely to matters of internal agency practice, general notice of proposed rulemaking is unnecessary.

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43 FR 30793
Published 7/18/78
Effective 7/18/78

PART 2—RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS

Notice of Hearing

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Commission is revising its rules of practice to provide specifically for thirty (30) days FEDERAL REGISTER notice of the time and place of the initial hearings to be held on applications seeking construction permits for production or utilization facilities. Once this notice has been given, the presiding office may reschedule the commencement of the hearing for a later date or reconvene a recessed hearing without again providing thirty (30) days notice.

EFFECTIVE DATE: July 18, 1978.

FOR FURTHER INFORMATION CONTACT:

Trip Rothschild, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, 202-634-1465.

SUPPLEMENTARY INFORMATION: Because this amendment relates to agency procedure, good cause exists for omitting notice of proposed rulemaking and public procedure thereon. It also may become effective without the customary 30-day notice. Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendment to Title 10, Chapter I, Code of Federal Regulations, Part 2 is published as a document subject to codification.

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43 FR 46292
Published 10/6/78
Effective 11/6/78

Distribution of Applications and Environmental Statements to Local Officials

See Part 51 Statements of Consideration.

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44 FR 4459
Published 1/22/79
Effective 1/22/79

PART 2—RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS

Clarification of Computation of Time Provisions

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final Rule.

SUMMARY: The Nuclear Regulatory Commission is amending certain provisions of its Rules of Practice to clarify the requirements for computing the time prescribed for replying to a petition for leave to intervene.

EFFECTIVE DATE: January 22, 1979.

FOR FURTHER INFORMATION CONTACT:

Marc R. Staenberg, Regulations Division, Office of the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, TEL: (301-492-8689).

SUPPLEMENTARY INFORMATION: The Nuclear Regulatory Commission has become aware that some confusion has arisen in regard to the time allowed for answering a petition for leave to intervene. Prior to this amendment, § 2.714(c), provided that answers to a petition for leave to intervene must be filed within a prescribed period after *filing* of the petition. In § 2.710, Computation of Time, the prescribed period for taking some action, such as filing an answer, runs from *service* of the initiating document.

The Nuclear Regulatory Commission intended § 2.710 to generally govern computation of time, including the provision for additional time for mailing. Therefore, a minor clarifying amendment is being made to § 2.714(c) to make clear that the time for replying to a petition to intervene shall be computed from the date of service of the petition.

Standard practice calls for notices of hearing and notices of proposed action to include the names and addresses of the Commission staff and applicant so that they may be served with copies of intervention petitions. This practice will be continued. If for some reason an intervention petition is not served by the petitioner, then the time for answer may be calculated from the date of service by the Secretary of the Commission.

Because these amendments relate solely to corrections and minor procedural matters, the Commission has found that good cause exists for omitting notice of proposed rulemaking, and public procedure thereon, as unnecessary, and for making the amendments effective on January 22, 1979, without the customary 30 days notice.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendment to Title 10, Chapter 1, Code of Federal Regulations, Part 2 is published as a document subject to codification.

44 FR 47758
Published 8/15/79
Effective 8/15/79

10 CFR Part 2

Rules of Practice; Selected Nuclear Power Plant Construction Permit Applications

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is adopting minor procedural amendments to permit the use of new staff procedures on a trial basis for the systems and site safety portions of selected nuclear power plant construction permit applications.

EFFECTIVE DATE: The amendments are effective on August 15, 1979.

FOR FURTHER INFORMATION CONTACT: Royal J. Voegeli, Office of the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone (301) 492-8693.

SUPPLEMENTARY INFORMATION: On April 18, 1979, the U.S. Nuclear Regulatory Commission published in the **Federal Register** (44 FR 23089–23090) for public comment proposed amendments to its regulations in 10 CFR Part 2 which would permit the use of new staff procedures on a trial basis for the systems and site safety portions of selected nuclear power plant construction permit applications. Interested persons were invited to submit written comments concerning the proposed amendments by June 4, 1979.

Only one comment was received, which questioned whether use of the new procedures would result in reducing the time for the issuance of the staff Safety Evaluation Report from approximately 18 months to 6 months. The commentor suggested that if such a reduction is practical, the regulations should be amended further to require that the Safety Evaluation Report be issued within 6 months after the application has been docketed.

The regulations never have specified a time limit for completion of the staff's Safety Evaluation Report. A safety or environmental review is completed after the staff is satisfied that it has all the information needed to complete its evaluation. The setting of a deadline might impose unwarranted pressures on the staff to complete licensing reviews prematurely. Certainly, the staff continuously seeks and implements changes which will improve the efficiency and effectiveness of the review process without compromising review quality. The amendments relate to new staff procedures which seek to implement such a change. It is believed that the much more comprehensive predocketing review to be made under the new procedures, coupled with improved staff-applicant coordination prior to tendering of the application, should enable the staff to realize its goal of completing the Safety Evaluation Report within six months of docketing. However, the six (6) month schedule must be recognized as only a goal, and therefore should not be made a regulatory requirement.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, and sections 552 and 553 of title 5 of the United States Code, the following amendments to 10 CFR Part 2 are published as a document subject to codification.

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44 FR 60715
Published 10/22/79
Effective 10/22/79

10 CFR Parts 2 and 50

Licensing of Production and Utilization Facilities; Antitrust Review Procedures

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is hereby amending current regulations to reduce or eliminate the requirements for submission of antitrust information in certain "de minimis" instances and to clarify requirements for antitrust review of applications for licenses for class 103 facilities (commercial facilities) other than power reactors.

EFFECTIVE DATE: October 22, 1979.

FOR FURTHER INFORMATION CONTACT: Mr. Argil Toalston, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone 301–492–8339.

SUPPLEMENTAL INFORMATION: Each applicant for a license for a production or utilization facility under section 103 of the Atomic Energy Act of 1954, as amended, is required by § 50.33a of 10 CFR Part 50, Licensing of Production and Utilization Facilities, to respond to a series of questions provided by the Attorney General of the United States in connection with the review of antitrust matters pursuant to section 105c of the Atomic Energy Act of 1954, as amended. In the case of a nuclear power reactor, several utilities may join in a single application for a license. Some of the participants will hold very small shares of the facility and will be entitled to only small percentages of the total output of electricity from the facility.

Generally, participants holding a small share entitling them to a small percentage of the electricity generated by the facility tend to be small entities not normally having a significant competitive impact in their general area. Consequently, on April 26, 1978, the Commission caused to be published in the **Federal Register** (43 FR 17830) a notice of proposed rule making waiving the requirement that "de minimis" participants in nuclear power plants submit antitrust information specified in Part 50, unless specifically requested by the Commission to do so.

The NRC received comments from the law firm of LeBoeuf, Lamb, Leiby & MacRae (LeBoeuf) addressing the **Federal Register** Notice. Based on these comments, the Commission has adopted LeBoeuf's suggestion that threshold levels for determining whether an electric utility may be considered "de minimis" for antitrust purposes should be based on the generating capacity of the applicant at the time of its application rather than its entitlement to electrical output from the facility. Using generating capacity would provide a more direct measurement of the relative size, and thus competitive impact, of an applicant.

Thus, the Commission has concluded that participants whose generating capacity at the time of application is 200 MW(e) or less are not required to submit information specified in Appendix L of Part 50, unless specifically requested by the Commission to do so. The Commission notes that the limit of 200 MW(e) of generating capacity would currently require approximately the 200 largest electric utilities in the United States to respond to all or a portion of NRC's antitrust questions. The Commission believes that utilities smaller than these generally would have a negligible effect on competition. However, under certain circumstances these smaller systems could also be required to submit the information set forth in Appendix L of Part 50 if possible antitrust problems become apparent.

The Commission has also concluded that participants whose generating capacity at the time of application is more than 200 MW(e) but not more than 1400 MW(e) are required to respond only to Question 9 in Appendix L of Part 50. Question 9 deals with neighboring, non-affiliated electric utility systems with peak loads smaller than applicant's. Such applicants could, of course, subsequently be specifically requested by the Commission to submit all the information required by § 50.33a. The Commission notes that the limit of 1400 MW(e) of generating capacity would currently require approximately the 100 largest utilities in the United

States to respond to all of the antitrust questions.

These proposed changes would reduce the burden of preparing antitrust-related data on small applicants, while at the same time maintaining an adequate standard of antitrust review. The Antitrust Division of the Department of Justice has concurred in the Commission's proposed action.

Other commercial production and utilization facilities in addition to nuclear power reactors are subject to antitrust review requirements. Amendments are proposed to Parts 2 and 50 in order to clarify that the antitrust review associated with construction permit applications for uranium enrichment facilities and fuel reprocessing plants may also call for submission of information by the applicant.

Because this rule making action reduces the burden on the resources of both the NRC staff and certain applicants without increasing the burden on anyone else, good cause exists for omitting a value/impact analysis.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 and section 553 of Title 5 of the United States Code, notice is hereby given that the following amendments to Title 10, Chapter 1, Code of Federal Regulations, Parts 2 and 50, have been adopted.

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44 FR 61320
Published 10/25/79
Effective 11/26/79

10 CFR Part 2

Rules of Practice for Domestic Licensing Proceedings; Petitions for Rule Making

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is issuing amendments to its "Rules of Practice" regarding the filing and processing of petitions for rule making. The amendments require the petitioner to include a statement in support of the petition setting forth the specific issues involved, the petitioner's views regarding those issues, and relevant technical, scientific, or other data involved which is reasonably available to the petitioner. The amendments will facilitate the processing of petitions for rule making.

EFFECTIVE DATE: These amendments become effective on November 26, 1979.

FOR FURTHER INFORMATION CONTACT: J. M. Felton, Director, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Tel: (301) 492-7211.

SUPPLEMENTARY INFORMATION: The Nuclear Regulatory Commission published a notice of proposed rule making in the Federal Register on April 28, 1978 (43 FR 18195) to amend 10 CFR Part 2.

The proposed amendment of § 2.802 set out in the April 28, 1978, notice would require a person filing a petition for rule making to state clearly and concisely the petitioner's grounds or interest in the action requested and to include a statement in support of the petition setting forth the specific issues involved, the petitioner's views or arguments with respect to those issues, relevant technical, scientific, or other data involved which is reasonably available to the petitioner, and such information as the petitioner deems necessary to support the action sought.

It was proposed also to add language stating (a) that a prospective petitioner is encouraged to confer with the staff prior to the filing of a petition for rule making, and (b) that questions regarding applicable NRC regulations sought to be amended, procedures for filing a petition for rule making, or requests for a meeting with the appropriate NRC staff to discuss a petition for rule making should be addressed to the Division of Rules and Records, Office of Administration.

Four letters of comment were received on the proposed rule. Three letters supported the proposed amendments. The fourth letter suggested a number of changes.

The Power Authority of the State of New York stated that the proposed amendments would be beneficial to all parties affected by a petition for rule making in that the issues involved would be clearly delineated and the consequent greater understanding of the concerns of the petitioner would lead to a more efficient and expeditious resolution of those concerns.

Consumers Power Company stated that the proposed amendments would help streamline the process through early resolution of misunderstandings and procedural problems, and would result in a more workable and equitable process.

Dow Chemical, U.S.A., favored the proposed rule, but recommended that the following statement, or its equivalent, be added to the proposed § 2.802(c)(3):

> The petitioner must submit information showing why current regulations and licensing practices are not adequate and how a new rule would alleviate this situation.

It is the Commission's view that the language set out in the proposed rule adequately covers the type of information to be submitted in support of a petition. Further, a petitioner may describe an inadequacy, but be unable to show specifically how to alleviate the situation. Accordingly, this suggestion has not been adopted.

A fourth letter of comment by Public Citizen Litigation Group (Public Citizen), made the following general statement:

> Public Citizen is concerned that the proposed amendment to 10 CFR 2.802, governing petitions for rule making to the Nuclear Regulatory Commission (NRC) may result in staff rejection of valuable and important citizens' petitions. Furthermore, because of the vagueness of the standards in the proposed regulations, there is danger of staff abuse of its discretion. The hurdle represented by these newly imposed requirements enforced by staff rejection of "deficient" petitions may deter citizens from petitioning the NRC . . .
>
> Public Citizen agrees with the premise of the proposed rule, that petitions to the NRC are more useful and likely to be adopted if they are well supported an well presented . . .

Public Citizen offered several specific comments as follows:

> Section 2.802(b) encourages consultation with the NRC staff on a prospective petition. Section (f) permits rejection of a petition by the staff, after one opportunity for revision, for failure to meet the standards of section (c). Consultation with the NRC staff could make available to a petitioner a valuable resource, resulting in greater efficiency and quality for all concerned. The officially encouraged consultation has the potential drawback of having a citizen's concerns steered in ways the NRC staff considers more desirable and "realistic." When the consultation is combined with the power to reject the petition as inadequately presented, the danger of manipulation and deterrence becomes great, especially for unsophisticated petitioners.

It is the intent of the Commission that its staff be available to assist petitioners in filing a petition if the petitioner requests such assistance. Consultation with the NRC staff is not required. The Commission intends that such consultation, if requested, will be of assistance to the petitioner and will be rendered in an objective manner. The NRC staff will not require modifications of the substance of a petition. This should result in petitions which satisfy the procedural requirements of § 2.802 and are in a proper form for consideration on the merits. Further, the decision to return a petition to the petitioner will be made by the Executive Director for Operations (EDO), and the Commission will be informed of this action. It should also be noted that, in these situations, the EDO is not rejecting the petition, but rather returning it to the petitioner without prejudice for failure to meet the procedural requirements of § 2.802. There is also no intent that the petitioner have just "one opportunity" to clarify the petition.

The Commission considers that it is appropriate for the EDO to make the determination as to whether a petition meets the procedural requirements of § 2.802. In this regard, the EDO already has the authority, pursuant to 10 CFR 1.40(o), to deny a petition for rulemaking of a minor or nonpolicy nature where the grounds for denial do not substantially modify existing precedent. Moreover, the Commission always retains its inherent supervisory authority over staff actions.

Public Citizen states further that:

> The trouble with requiring presentation of the desired product of the proposed rulemaking is that some problems are too complex or unexplored for a petitioner to propose a definite solution. For example, the PIRG decommissioning petition proposed imposition of financial guarantees of eventual decommissioning. However, the petitioners, who are reasonably well informed, could not say what would be a realistic estimate of the needed funds or what financial guarantee arrangements would be available. The situation is similar with respect to the analogous petition of the Natural Resources Defense Council (NRDC) on financial guarantees of safe windup of uranium mills. . . . It should suffice for a petition to document the existence of a problem, suggest the direction of a solution, without detailed provisions or numerical standards, and to ask the NRC to apply its expert knowledge to study and solve the problem.

The Commission agrees with the comment that a petitioner should not be expected to furnish detailed provisions or numerical standards or a precise rule, designed to solve the problem which the petitioner has documented. The Commission's staff will evaluate the merits of a petition, and develop an appropriate solution to such problems, including the preparation of proposed amendments of NRC regulations as may be indicated. Although a petitioner may highlight the existence of a problem and suggest the general direction of a possible solution, the Commission's staff will be responsible for the development of a proposed rule if the staff study indicates a need for amendment of NRC regulations. To clarify the Commission's intent, paragraph (c)(1) has been modified to provide that the petitioner may set forth a general solution to the problem identified rather than the specific text of a proposed amendment.

Public Citizen questions the proposed provision § 2.802(c)(2) that each petition shall state clearly and concisely the petitioner's grounds or interest in the action requested. Public Citizen states that:

> Statement of petitioner's "interest" in the matter smacks of a standing requirement. Public Citizen would be dismayed if the NRC intended to impose judicial standards of standing to filing a petition for rulemaking as it has chosen to do for intervention in nuclear export license proceedings. . . . Public Citizen does not suppose that a standing requirement is intended, but this should be clarified, along with clarification of what is intended and why.

Pursuant to the Administrative Procedure Act, as amended, the right to petition must be accorded to any "interested persons". The Commission has always construed these terms broadly in accepting petitions for rulemaking and has no intention of rejecting a petition for rulemaking solely on the ground that a petitioner has not alleged an injury in fact of the same character that would be necessary for standing in a licensing proceeding.

Public Citizen proposes a number of procedural steps for the processing of petitions, including time limitations for the determination of petitions. The Commission has concluded that it is impracticable to incorporate such procedures into the text of § 2.802. In many respects the proposed procedures would be administratively inefficient and wasteful of the Commission's time. Internal procedures have been established whereby the staff initially reviews petitions, establishes priorities in processing petitions, and initiates necessary studies. The Commission and the public are informed on a quarterly basis of the status of each petition. Many petitions are complex from a technical or legal view and it is more efficient for the staff to make the initial evaluation and to recommend a course of action rather than for the Commission to process petitions initially and direct the staff with respect to disposition of the petition.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 2, are published as a document subject to codification.

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44 FR 67088
Published 11/23/79
Effective 11/30/79
10 CFR Part 2

Review of Uncontested Matters by Adjudicatory Boards During Operating License Proceedings

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its Rules of Practice to provide that during an operating license proceeding, NRC adjudicatory boards may examine any "serious" matter not contested by the parties. The rules as now written provide that the adjudicatory boards may review matters not put in issue by the parties to an operating license proceeding only in "extraordinary circumstances," and must exercise this authority "sparingly". The amended rules eliminate an apparent constraint on boards as well as more accurately reflect current NRC adjudicatory board practice.

EFFECTIVE DATE: November 30, 1979.

FOR FURTHER INFORMATION CONTACT: William M. Shields, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Phone: 202-634-3215.

SUPPLEMENTARY INFORMATION: The Commission's rules governing review of uncontested matters in operating license proceedings are: 10 CFR 2.760a, 10 CFR 2.104(c), 10 CFR Part 2, Appendix A, Sec. VIII(b) [Licensing Boards]; 10 CFR 2.785(b)(2) and 10 CFR Part 2 Appendix A, Sec. IX(a) [Appeal Board]. In general, these rules provide that in operating license proceedings the boards may review "serious" matters not put in issue by the parties only in "extraordinary circumstances", and that this authority is to be used "sparingly". The rules derive from a decision of the Atomic Energy Commission entitled *Consolidated Edison Company of New York* (Indian Point), 8 AEC 7 (1974).

It has come to the Commission's attention that this wording could prevent boards from examining issues that, although not presented by "extraordinary circumstances," could still pose important health and safety questions. It is true that members of the current adjudicatory boards, while limiting their inquiries to "serious" matters involving the public health and safety, the environment, or the common defense and security, do not appear to have further constrained themselves by strict observance of the "extraordinary circumstances" and "sparingly" criteria. The Commission approves this somewhat less restrictive limitation, and thus amendments to the rules of practice are in order.

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45 FR 3250
Published 1/17/80
Effective 1/17/80
Comment period expires 2/19/80

10 CFR Part 2

Rules of Practice for Domestic Licensing Proceedings

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Immediately Effective Final Rule with request for comment.

SUMMARY: The Commission has decided to delegate to its Executive Director for Operations the authority to issue Orders to licensees during an emergency. This decision necessitates amendments to certain provisions of the NRC rules concerning the procedures for imposing requirements by Order. The amendments are being adopted without notice of proposed rulemaking because it is a rule of agency organization, procedure, or practice. Interested persons may submit written comments on the amendments to NRC. The amendments are immediately effective for good cause in accordance with section 553(d) of the Administrative Procedure Act (5 U.S.C. 553(d)).

DATE: The amendments are effective on January 17, 1980.

Comments must be received on or before February 19, 1980.

ADDRESSES:: Interested persons may submit comments to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch.

FOR FURTHER INFORMATION CONTACT: C. W. Reamer, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Telephone 202/634-3288.

SUPPLEMENTARY INFORMATION: The Executive Director for Operations has important responsibilities with respect to the NRC Incident Response Organization. He is a member of the Executive Management Team (EMT). An overall goal of the Incident Response Program is to assure that proper actions are taken to protect public health and safety in the event of an incident involving NRC-licensed activities. The EMT manages NRC's response to such incidents and would, in an appropriate case, direct a licensee to take specified actions to protect public health and safety.

The EDO's responsibilities with respect to NRC Incident Response could entail the issuance of Orders to licensees. However, the EDO has not been delegated authority to issue Orders in emergencies by the Commission. Other staff members of the EMT have such authority.

The Commission has decided to delegate authority to the EDO to issue Orders to licensees in emergencies. The delegation shall be effective until cancelled or superseded by the Commission. In exercising the authority, the EDO may determine whether an emergency exists. The statutory authorization for this delegation is found in Section 201 and Section 209 of the Energy Reorganization Act of 1974 (42 U.S.C. §§ 5841 and 5849), and Section 161 of the Atomic Energy Act of 1954 (42 U.S.C. § 2201). The purpose of the delegation is to give the EDO authority for such Orders to licensees as he may issue during an emergency in connection with his responsibilities as part of the NRC's Incident Response Organization and the EMT. This authority is to be exercised by the EDO in accordance with law and the policies of the NRC. The authority may not be redelegated.

The authority of other NRC officials is not affected by this delegation. Section 2.204 of the NRC Rules which, by Commission understanding, authorizes action by staff officials shall be understood to authorize EDO action during an emergency.

General notice of proposed rulemaking is dispensed with under 5 U.S.C. 553(b) because the amendments concern rules of agency organization, procedure, or practice. Because it is necessary that the EDO have all necessary authority immediately, in case of an emergency, the Commission finds that good cause exists under 5 U.S.C. 553(d)(3), and the amendments are effective immediately. However, the new regulations are subject to modification in response to public comments, and comments on these amendments are invited.

Pursuant to the Atomic Energy Act of 1954 as amended, and sections 552 and 553 of title 5, United States Code, the following amendments to 10 CFR Part 2 are published as a document subject to codification.

45FR14199
Published 3/5/80
Effective 3/5/80

Minor and Clarifying Amendments

See Part 1 Statements of Consideration

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45 FR 45690
Published 7/8/80
Effective 7/8/80

10 CFR Part 2

Rules of Practice for Domestic Licensing Proceedings

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Commission is amending its rules of practice to provide more realistic time limits within which the Commission may determine whether to grant or deny petitions to review, and whether to review on its own initiative in such cases, a decision or action of the Atomic Safety and Licensing Appeal Board under 10 CFR 2.786.

EFFECTIVE DATE: July 8, 1980.

FOR FURTHER INFORMATION CONTACT: Mark E. Chopko, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC. 20555, 202-634-3224.

SUPPLEMENTARY INFORMATION: On May 2, 1977, the Commission issued a final rule which provided a procedure for parties to petition the Commission for a discretionary review of a decision or action of the Atomic Safety and Licensing Appeal Board. If twenty (20) days passed after the filing of a petition without Commission action granting it in whole or in part, the rule provided that the petition would be "deemed denied." However, since other parties to the proceeding were afforded a period of ten (10) days after service of a petition for review to file an answer opposing Commission review, the effective time for Commission consideration of the decision, petition and answers has a always been very short.

On April 26, 1978, the Commission issued miscellaneous amendments to its rules of practice which became effective on May 26, 1978. One of these amendments enlarged the time for parties "to do some act or take some proceeding within a prescribed period after the service of a notice or other paper upon him and the notice or paper is served upon him by mail" by providing that five days, rather than the previous three, be added to the prescribed period. 10 CFR 2.710. Accordingly, a situation has been created where a party opposing a petition for review which was served by mail, as is usually the case, has fifteen days after filing of the petition to file an answer. The Commission's rules provide that filing of documents, such as answers to petitions for review, will be deemed to be complete as of the time of deposit in the mail. 10 CFR 2.701. The answers likely may not actually arrive at the Commission for several days thereafter.

As a result of these rules, the

Commission's experience has been that in almost every case in which a petition for review is filed, an extension of the twenty-day period within which the Commission must decide whether to grant or deny it is necessary. Therefore, the Commission has decided to amend paragraph (b)(5) of § 2.786 to extend the period within which it may consider petitions to review to thirty (30) days, after which if it does not grant the petition in whole or in part, the petition shall be deemed denied.

On occasion confusion has been expressed about whether the time for exercising the Commission's discretion to review a decision or action on its own motion which is addressed in paragraph (a) of 10 CFR 2.786 is automatically extended when a petition for review has been filed to coincide with the schedule established for consideration of petitions in paragraph (b). In almost every instance, the latter period may extend beyond the thirty (30) days now afforded by paragraph (a). The Commission recognizes that cases may occur in which it will determine that issues raised by a petition do not warrant review, but will elect to review on its own motion an issue not pressed by any party. In order to clarify that aspect of its regulations, the Commission has decided to amend paragraph (a) of 10 CFR 2.786 to provide that the time within which it may determine whether to review a case on its own motion is thirty days from the date of decision or action when no petitions for review are filed, or thirty (30) days after a petition has been filed, that is, co-extensive with the times described in § 2.786(b)(5).

Because this amendment relates solely to matters of agency procedure, notice of proposed rulemaking and public procedure thereon are not required by section 553 of Title 5 of the United States Code and shall be omitted from this proceeding. As a rule applying only to internal agency procedure, this final rule shall be effective upon publication in the **Federal Register**.

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45 FR 49535
Published 7/25/80
Effective 7/25/80

10 CFR Part 2

Procedural Assistance in Adjudicatory Licensing Proceedings

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Effective rule.

SUMMARY: NRC is amending its regulations in order to provide a one-year pilot program of procedural assistance in adjudicatory proceedings on applications for licenses and amendments thereto, except for antitrust proceedings, to parties other than the applicant by (a) upon a party's request, providing one transcript without charge to that party and (b) upon a party's request, copying and serving without charge that party's testimony (including attachments), proposed findings of fact and conclusions of law, and responses to discoverey requests. In addition, the regulations are amended to require that parties, including an applicant, file with NRC an original plus two copies of each filing in an adjudication, rather than an original and twenty copies.

EFFECTIVE DATE: July 25, 1980.

FOR FURTHER INFORMATION CONTACT: Thomas F. Dorian, Esq., Office of the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (Telephone: (301)-492-8690).

SUPPLEMENTARY INFORMATION: In order to help parties assist the Commission in arriving at its decisions, the Commission on several occasions over the past several years has considered proposals to reduce cost burdens for parties in Commisson adjudicatory licensing proceedings on applications for licenses and amendments thereto. Several proposals were considered in the context of the S-3 rulemaking on the uranium fuel cycle. See 42 FR 13803 (March 13, 1977), 43 FR 6915 (April 14, 1978), and 44 FR 45362 (August 12, 1979). From that proceeding the Commission hoped to gain specific experience with providing free service of documents and free transcripts and to use the experience to develop general policy with respect to adjudicatory proceedings.

Eligibility for NRC Procedural Assistance

One alternative with respect to procedural assistance is to provide it to full participants, i.e., parties, who submit an affidavit to the Hearing Board stating, with brief factual support, that their ability to participate would be significantly impaired without this assistance. Under this alternative the Commission would have had to provide the Boards and parties with some guidance as to who would ordinarily qualify for assistance under this standard. However, offering procedural assistance to all intervenors without qualification might offer enough savings, from not having to decide who was qualified to receive assistance, to be worth the extra expense of assisting a few additional intervenors. On the other hand, it is incongruous to charge an applicant from $50,000 to $1 million for processing an application, and then to offer it a free transcript, worth on the order of $1,000.

On balance, the Commission has decided that the better alternative is to provide procedural assistance to all parties other than an applicant in adjudicatory proceedings on applications for licenses and amendments thereto.

NRC Provision of Free Transcripts

Transcripts are usually expensive, especially when fast copy is requested. A typical transcript for one day of a proceeding runs about 200 pages. The original of such a transcript, provided the next morning, costs about $1,000; supplementary copies cost about $100. In the S-3 proceeding, transcripts were requested by most public interest groups, industry representatives and utilities. The principal conclusion that can be drawn from that proceeding is almost self-evident, namely, that NRC's offer to provide an expensive service (transcripts) is attractive to most parties. These parties, in turn, can better assist the Commission in arriving at its decisions.

There is no reason why free transcripts could not be made available in adjudications to parties, other than the applicant, at the same time and location as they are made available to the NRC staff. If transcripts are mailed to the staff, they would also be mailed to intervenors. This service could replace present practice where members of the staff or the Licensing Board frequently lend an intervenor an extra copy of the transcript, although on a necessarily irregular basis. Transcripts are particularly important to the many intervenors who attempt to make their cases on cross-examination.

Therefore, the Commission has decided to initiate a one-year pilot program to provide free transcripts on the basis previously described. Licensing Boards will have the discretion to control the distribution of transcripts to parties—for example, to limit distribution to some but not all of a consolidated group of intervenors, or to only those phases of a hearing in which an intervenor intends to participate.

NRC Provision of Free Copying and Service

Most licensing proceedings produce dozens of filings. It should be noted that, frequently, parties in complex proceedings routinely serve more people than necessary. Particularly in those proceedings in which certain aspects of an issue have been heard before all levels of NRC adjudicatory boards, parties tend to compile service lists which reflect the entire history of the proceeding, rather than being tailored to the particular paper being filed. Random checks of service lists show that this sort of error accounts for between 3 and 7 extra copies made and distributed. The Commission wishes to emphasize that parties should be aware that service is required only on the Commission or the pertinent adjudicatory board and the parties, and that parties endeavoring to hold down their costs should carefully monitor their service lists.

In December 1977, the Commission authorized the Docketing and Service Branch to copy and serve submissions in the S–3 proceeding, if requested to do so by parties to the proceeding. Each party requesting this assistance served an original and two copies on NRC. Others followed normal procedures, namely, service on other parties and an original plus 20 copies on NRC.

The results show that the availability of free copying and service had no discernible impact on the length or frequency of filings with the Commission. Concern had been expressed that free service would encourage abuses in the form of overlong, unedited or unnecessary filings. In general, for those who ultimately requested copying and service, there were no significant differences in length or frequency between filings copied and served by the parties themselves and those copied and served by NRC at a party's request.

This experience suggests that a program of free NRC copying and service is not likely to be abused. The Commission does not wish to assume this responsibility for all classes of documents, since this would create substantial delay. It has, however, identified several categories of documents which are bulky, but do not arise frequently. Their service by the Commission would thus relieve parties of a substantial burden without introducing substantial delay. These categories are: (1) testimony (including attachments), (2) proposed findings of fact and conclusions of law, and (3) responses to discovery requests. In relative terms, service of these documents need not be as rapid as items such as briefs or motions. A rough look at filings in licensing proceedings, indicates that these documents tend to be relatively bulky. Also, documents containing testimony and exhibits contain substantive contentions and are, in effect the "essence" of NRC proceedings. By processing them, NRC would be copying and serving a substantial amount of the number of pages filed, a service which would have high payoff in terms of reducing costs to intervenors, without substantially impeding the progress of the adjudicatory process.

Copying and service of these documents by the commission may cause some very small delay in the hearing process. A licensing proceeding may require several rounds of testimony and an opportunity to file proposed findings of fact and conclusions of law. (Responses to discovery requests are also filed, but not on a tight time schedule.)

At least five days would be required for each set of documents to reach the Commission and be copied and mailed to the parties and board members. Therefore, the rule provides that documents filed with Docketing and Service in the three categories previously described should be filed not less than five days before the date at which they are submitted to an adjudicatory board, unless the presiding officer provides otherwise.

On balance, the Commission has decided to undertake a one-year pilot program of free copying and service. Copying and service have been requested by intervenors in a number of instances and the value of the assistance, both to intervenors and the quality of Commission decisionmaking, may be worth the modest delay entailed. A one-year pilot program would allow NRC to obtain information on this effort and on any problems such a program may present, as well as answer whether NRC copying and service of testimony is an incentive to timely filing.

Filing of 20 Copies with the Commission

Parties in licensing proceedings, under 10 CFR 2.708(d), file or serve documents as follows: the original and 20 copies with the Commission, and one copy on each party and on members of the hearing panel in question. The 20 copies filed with Docketing and Service are for the Commission's convenience for internal informational distribution; the appropriate Board and the parties are served separately.

These 20 copies are not adequate for internal NRC distribution needs. In practice, Docketing and Service distributes some copies upon receipt; making additional copies creates a time lag of up to several days. Since the copies Docketing and Service sends out are informational, the Commission perceives no tight time constraint on internal information distribution; the normal time lag necessary to allow NRC to do all copying of internal distribution documents would not cause inconvenience. Therefore, the Commission has decided that all parties, including applicants, need file with the Commission only an original and two copies; the original would go to the docket file, one copy would go directly to the Public Document Room, and the other copy would be used for reproduction.

Antitrust Proceedings

NRC will not provide free transcripts and free copying and service in antitrust proceedings. The studies of filings have been confined to health, safety, and environmental licensing proceedings. While the Commission believes that the changes would substantially assist intervenors in those proceedings without introducing substantial delay, it does not know whether these conclusions can be extended to antitrust proceedings. There may be, in fact, substantial differences in the extent and general bulk of discovery between the two kinds of proceedings. In addition, the Commission does not know whether parties in antitrust proceedings are likely to need such assistance as intervenors in health, safety, and environmental proceedings. Consequently, the Commission will investigate this area further before making any changes.

Because these amendments relate solely to agency procedure and practice, the Commission has found that good cause exists for omitting notice of proposed rulemaking, and public procedure thereon, as unnecessary, and for making the amendments effective immediately without the customary 30 days notice.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter 1, Code of Federal Regulations, Part 2 is published as a document subject to codification.

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45 FR 62067

Published 9/18/80

Effective 9/18/80

Rules of Practice; Special Assistants Used by Atomic Safety and Licensing Boards

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its "Rules of Practice" to permit NRC Atomic Safety and Licensing Boards to use special assistants to be drawn from the membership of the Atomic Safety and Licensing Board Panel. The special

assistants may be allowed to participate as technical interrogators, alternate Atomic Safety and Licensing Board members, special masters (with consent of the parties), or consultants. The purpose of the amendments is to facilitate the hearing process and improve the quality of the record produced.

DATE: The rule shall be effective September 18, 1980.

FOR FURTHER INFORMATION CONTACT: Mark E. Chopko, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC, 20555 (telephone 202/634-3224); Bruce A. Berson, Office of the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, DC, 20555 (telephone 301/492-7678).

SUPPLEMENTARY INFORMATION: In 1979, the Commission appointed a Task Force to study the use of part-time members of the Atomic Safety and Licensing Board Panel (referred to herein as ASLBP) and recommend any necessary or desirable changes regarding the use of those employees. In October 1979, the Task Force published its report and based on its surveys and interviews reached a series of findings with respect to them. Part-time ASLBP members provide the NRC access to a wide variety of expertise that could not be duplicated in a full-time staff except at considerable expense to the Government. Part-time members also offered a greater range of viewpoints on the ASLBP and more ready access to current knowledge in a particular field. Further, part-time members have aided the public perception of objectivity in the NRC licensing process. For all these reasons, the Task Force concluded that part-time ASLBP members are an important asset to the NRC. Rather than lose the benefits of those employees as hearings grew longer and more intensive, the Task Force specifically recommended that the Commission explore the use of part-time ASLBP members as "special assistants" to the Boards, to serve as "technical interrogators," "alternate board members," "special masters," or "consultants" to aid the hearing process and improve the quality of the record produced. On January 23, 1980, the Commission published proposed rules for comment in response to those recommendations. 45 FR 5308. Each aspect of the proposed rules is described below.

Only two comments were received. While generally agreeing with the thrust of the rules, both raised questions about the proposed amendments to permit "alternate board members" and "special masters." In large measure, the commentators objected to both the master and the alternate member, arguing that the Atomic Energy Act does not contemplate more than three members to a licensing board (42 U.S.C. 2241(a)), that the Administrative Procedure Act (5 U.S.C. 551 *et seq.*) does not contemplate this arrangement or permit delegation of the hearing function (including that of the presiding officer or decisionmaker), and that the Licensing Board should not entertain "expert" viewpoints not subject to cross-examination. The Commission has examined these comments in light of the specific statutory provisions noted and, while it does not agree with much of the arguments raised, concludes that the proposed rule on use of "special masters" should be modified to provide for their use only on consent of the parties. No fundamental change is necessary to the proposed rule on alternate board members but a more clear explanation of their role is provided.

The Atomic Energy Act amendments that added section 191 (42 U.S.C. 2241) contemplated that a three-member board would preside at licensing hearings in lieu of a single hearing examiner. Those amendments also provided that one member should be "qualified in the conduct of administrative proceedings," that is, a lawyer, who by custom has been the Chairperson of the Licensing Board. In addition, the Administrative Procedure Act generally contemplates that the person who presides over the reception of the evidence should make the decision, although this is not required in determining applications for initial licenses and in certain other types of cases. The use of special masters without the consent of the parties, as contemplated in the proposed rule (10 CFR 2.722(a)(2)) arguably could violate these principles by having a technical expert hear the evidence and "preside" at that hearing, weigh credibility and decide major, perhaps crucial, issues in a case, and then recommend a decision. Requiring *de novo* review by the Licensing Board or some alternative where a party may sponsor the master's report subject to the other party's objections or comments might cure these defects but would effectively delay the proceeding, waste resources, and offset the advantages that would be expected from use of the special master. Since parties may consent to procedures which differ from those statutorily provided, and since the Commission believes that a "special master" could be invaluable in developing the record and conserving Board time, the Commission will modify the proposed rule to provide that a special master may be used with consent of the parties. *Cf. Toledo Edison Co., et al.* (Davis-Besse Nuclear Power Station), ALAB-300, 2 NRC 752 (1975) (describing the use of a master with consent of the parties to rule on privilege objections to documents sought by party discovery in an antitrust proceeding).

On the other hand, the use of an "alternate board member" [1] does not arguably violate the statutory principles discussed above. The use of an alternate board member will not require a separate hearing or proceeding as would use of a special master. The alternate board member will sit with the three-member licensing board, will ask questions, comment upon testimony and provide his advice on the record and in the presence of the parties to the licensing board. The licensing board will still preside at the reception of the evidence, will still rule on issues of credibility and admissibility and will decide all issues in the case. The recommended decision of the alternate board member will be made on-the-record with an opportunity for the parties to comment thereon. The licensing Board Panel's practice of avoiding off-the-record communications between the Board and other Panel members on any fact in issue will apply to communications between the Board and the alternate after the alternate's report has been received. Thus no party will lose any statutory rights and each party will be given an opportunity to provide views and comments on the alternate member's reports to the Licensing Board. In addition, that party aggrieved by any decision of the Board, based in part on an alternate member's decision, will have an opportunity to appeal that decision to the Atomic Safety and Licensing Appeal Board. Thus the Commission believes that no changes are necessary to the proposed rule on use of alternate board members as clarified above.

The Commission adopts final rules on the use of part-time ASLBP members as follows:

Section 2.722(a)(1) provides for technical interrogators who may assist the presiding officer during the hearing by examining witnesses. The interrogator will play no part in the decision and will provide no advice to the Board. No changes are necessary to the proposed rules. *See* 45 FR 5308.

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[1] The term "alternate board member" as a "special assistant" should not be confused with use of the term "alternate" in 10 CFR 2.721(b). In the latter situation the "alternate" is a substitute for a member of a Board who becomes unavailable. *See generally New England Coalition on Nuclear Pollution v. NRC*, 582 F.2d 87, 99–100 (1st Cir. 1978). In this rule (10 CFR 2.722(a)(3)), the "alternate" sits with the three-member Board and not instead of the Board or any of its members.

Section 2.722(a)(2) authorizes special masters to hear evidentiary presentations by the parties on specific technical matters and, upon completion of the presentation of evidence, to prepare a report that would become part of the record. Such use shall be upon consent of all the parties. The parties will have an opportunity to comment upon the report and may appeal evidentiary rulings to the presiding officer. The presiding officer will retain final decisionmaking authority over the issues heard and reported on by the special master. The proposed rule is modified to provide for consent of the parties.

Section 2.722(a)(3) authorizes an alternate board member to participate in that portion of the proceeding relating to his or her area of expertise and to report conclusions to the presiding officer. The alternate board member, as clarified above, shall ask questions, provide advice and provide a written record of his advice to the Board. However, the three-member Board shall preside at all sessions and rule on all questions of evidence and other motions directed during that portion of the proceeding. The Board shall also retain all decisionmaking authority. With the explanation provided in this supplementary information, no changes are necessary.

Section 2.722(b) authorizes consultants to brief the Board as described in the proposed rule. In addition, modifications to existing Sections 2.718 and 2.719 shall be made as described in the proposed rule. No changes are necessary to either of these proposals. 45 FR. 5308. A minor change to the proposed addition to Part 2, Appendix A has been made to avoid confusion in the use of the term "alternate board member" with the term "alternate" in 10 CFR 2.721(b).

Because the final rules are not substantive and relate only to matters of Board procedure and do not require any change in conduct on the part of any party, the rules are effective immediately when published in the Federal Register 5 U.S.C. 553(d). Licensing Boards, however, engaged in licensing hearings when the rule becomes effective should solicit the views of the parties before first using a special assistant. Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and Section 553 of the United States Code, notice is hereby given that the following amendments to 10 CFR Part 2 are adopted.

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45 FR 68919
Published 10/17/80
Effective 10/17/80

10 CFR Part 2

Changes in Rules of Practice Governing Summary Disposition on Pleadings

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations governing the authority of its presiding officers to consider motions for summary disposition of certain issues on the pleadings, 10 CFR Section 2.749, to permit parties to file answers supporting such motions.

EFFECTIVE DATE: October 17, 1980.

FOR FURTHER INFORMATION CONTACT: Bruce A. Berson, Office of the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Telephone (301) 492-7678.

SUPPLEMENTARY INFORMATION: Section 2.749 of the Commission's Rules of Practice for Domestic Licensing Proceedings, "Authority of presiding officer to dispose of certain issues on the pleadings," establishes a procedure whereby a party to an administrative proceeding may move the presiding officer to rule in that party's favor as to all or any part of the matters involved in the proceeding. The presiding officer will render the decision sought by the moving party if the filings in the proceeding show that there is no genuine issues as to any material fact and that the moving party is entitled to a decision as a matter of law.[1]

Section 2.749(a) now provides that "any other party may serve an answer *opposing the motion* [for summary disposition], with or without supporting affidavits, within twenty (20) days after service of the motion" (emphasis added). However, it has been a long-standing practice of the regulatory staff to file an answer to the motions of other parties for summary disposition—in support or in opposition, as appropriate.

The Commission has determined that the rule should be clarified to specifically permit responses in support of, as well as in opposition to, motions for summary disposition. Since important legal and procedural consequences flow from a presiding officer's grant or denial of a motion for summary disposition, the Commission believes that the views of its regulatory staff, as well as the views of other parties, should be considered and may be of substantial assistance to the presiding officer. Therefore, the Commission is clarifying § 2.749(a) to specifically permit responses from parties which support motions for summary disposition. The clarification will help ensure that the relevant issues are fully developed before the presiding officer rules on the motion and is consistent with the general policy of the Commission's Rules of Practice to encourage parties to express their views before adjudicatory tribunals. The amendment also harmonizes the Commission's summary disposition procedure with the provisions of 10 CFR 2.730(c), "Motions," which permit a party to file an answer in support of or in opposition to a motion filed by another party.

Since statements in support of a motion for summary disposition may raise facts and arguments not presented by the moving party and need not be served until the time at which an answer opposing the motion must be served, § 2.749(a) is also amended to permit the party opposing the motion to file a supplemental response in writing which addresses any new matters raised in supporting statements and not presented in the initial motion. The Commission expects its presiding officers to establish expeditious time limits on a case-by-case basis for the filing of any response to supporting statements, consistent with the requirements of fairness. This departure from Commission practice (which does not ordinarily allow further pleadings beyond the initial pleading and response thereto) is desirable here to avoid potential unfair surprise to parties opposing motions for summary disposition. No further supporting statements or responses thereto shall be entertained.

Because this amendment is not substantive and relates only to matters of agency procedure, notice of proposed rulemaking, and public procedure thereon, is unnecessary, and the amendment is effective on October 17, 1980 without the customary 30 days notice.

(5 U.S.C. 553(b) and 553(d))

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter 1, Code of Federal Regulations, Part 2 are published as a document subject to codification.

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[1] The procedure established in the rule may be used only for the determination of specific subordinate issues in any proceeding involving a construction permit for a production or utilization facility and may not be used to determine the ultimate issue as to whether a construction permit shall be authorized. Section 2.749(d).

45 FR 69877
Published 10/22/80
Effective 11/21/80

10 CFR Part 2

Changes in Rules of Practice Governing Discipline in Adjudicatory Proceedings

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations governing discipline in adjudicatory hearings, 10 CFR 2.713, to (1) reiterate the standard of conduct expected of participants in proceedings; (2) clarify who may appear before NRC in a representative capacity; (3) clarify and bolster the authority of the presiding officer, Appeal Board, and Commission to suspend any party or representative of a party from participation in a particular proceeding where, as a result of the party's or representative's conduct, this is necessary for the orderly conduct of the proceeding; and (4) specify special interlocutory appeal procedures governing suspensions from participation.

EFFECTIVE DATE: November 21, 1980.

FOR FURTHER INFORMATION CONTACT: Bruce A. Berson, Office of the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Telephone (301) 492-7678.

SUPPLEMENTARY INFORMATION: On January 18, 1980, the Nuclear Regulatory Commission published in the **Federal Register** (45 CFR 3594) a proposed amendment to its regulations, 10 CFR Part 2—"Rules of Practice for Domestic Licensing Proceedings," regarding representation and conduct of attorneys in adjudicatory proceedings. Interested persons were invited to submit comments for consideration in connection with the proposed amendment by March 3, 1980.

Four comment letters were received from interested persons during the 45 day comment period. The comments addressed the following issues:

1. The necessity for the rule;
2. The standards of conduct;
3. Representation at NRC proceedings;
4. The process of appealing suspensions; and
5. Referral of suspended attorneys to the state bar.

After careful consideration, the Commission has determined that no changes to the proposed rule based on the comments are necessary. However, the Commission has revised and broadened the process of appealing suspensions and made two other minor clarifications to the rule based upon its own review. The clarifications (1) add the words "or officer" to the second sentence of § 2.713(b) following "duly authorized member" to reflect actual practice and the intent of the rule; and (2) provide for mandatory referral of an attorney suspended for more than 1 day to the appropriate state bar even in the absence of an appeal. (Issues 3 and 5 below). The revision to the process of appealing suspensions is discussed below (Issue 4).

The public comments and changes made by the Commission are discussed below.

1. Necessity for the rule: Two commenters believe the rule is unnecessary. One suggests that the presiding officer has adequate existing authority under 10 CFR 2.718, "Power of the Presiding Officer," to control the conduct of the proceeding and the other states that local authorities could be called if a true disturbance were created. Although disciplinary authority may be implied from 10 CFR 2.718(e), the Commission believes it is preferable to specifically codify such authority and the associated procedures after public notice and opportunity for comment. The Commission also believes presiding officers and other NRC tribunals should have specific authority to discipline representatives in NRC proceedings, when necessary, without routinely requesting (or waiting for a situation to require) the assistance of local law enforcement authorities, as suggested by the second commenter.

2. Standards of conduct: Three commenters express the view that the types of conduct enumerated in proposed § 2.713(c)(1) which may result in the suspension of a representative from a proceeding are vague, overly broad, or subject to abuse by a presiding officer. One commenter also states that the meaning and consequence of "censure" are not defined.

The rule is designed to be read and applied in light of its purpose. Therefore, presiding officers will generally apply judicially developed precedents governing contempt in imposing and fashioning appropriate disciplinary sanctions. Since the presiding officer is charged with conducting a fair proceeding in a reasonable and even-handed manner, he or she is expected to apply the provisions of this rule in a similar fashion. The Commission recognizes that a presiding officer might, on occasion, erroneously suspend a representative from a proceeding for conduct not warranting such action. The appeal process provided in the rule would correct any such error. Therefore, the Commission expects no abuse of the disciplinary standards.

The Commission believes the meaning and consequence of censure are self-explanatory. Censure, public or private, is generally a more appropriate remedy for an isolated instance of misconduct than suspension. In addition, the rule makes clear what conduct is expected of representatives. (See generally, ABA Code of Professional Responsibility and Ethical Considerations, EC-7-34 through and including 7-39 and 8-5.)

3. Representation at NRC proceedings: One commenter suggests that "the restriction of attorney-at-law to only those admitted to the bar of U.S. or District of Columbia Courts or the highest court of any State, territory, or possession of the United States may well work to deprive public-interest intervenors of otherwise well-qualified counsel or other legal representation." The Commission believes the restriction is appropriate because admission before one of the specified courts is generally required before an attorney may be licensed to engage in the practice of law in a particular jurisdiction.

The Commission has determined that the words "or officer" should be added to the second sentence of § 2.713(b) following "duly authorized member." The clarification makes clear that a partnership, corporation or unincorporated association may be represented by a duly authorized *officer*, as well as by a member or attorney and reflects both actual practice and the intent of the rule.

4. Process of appealing suspensions: The provisions for appealing suspensions received a number of comments. Two commenters express concern that the appeals process requires a suspended individual to overcome a presumption of guilt and establish his or her innocence. The Commission disagrees with the characterization. Although there is some presumption that the action of a lower administrative tribunal is correct, the Commission or an Atomic Safety and Licensing Appeal Board need not accede to a lower board's decision simply because it is supported by "substantial evidence" or is not "clearly erroneous." See *Duke Power Company* (Catawba Nuclear Station, Units 1 and 2), ALAB-355, 4 NRC 397 (1976).

Another commenter recommends that a proceeding be automatically stayed whenever a representative is suspended for [illegible] or less. The commenter [illegible] disciplinary action ordinarily focuses on the conduct of the representative rather than the party and recommends that the "necessary to prevent injustice" standard governing the granting of a stay in § 2.714(c)(2) be [illegible]. She recommends instead that the party be given the option of electing either an automatic stay pending completion of the suspension (or final disposition of the appeal, if appealed) or a stay for a reasonable period of time in which to secure other representation.

The Commission believes that the proposed rule adequately protects the interests of an affected party by permitting a stay for a reasonable period of time in order to obtain other representation if necessary to prevent injustice. Whether a stay should be granted in a particular case should be left to the discretion of the presiding officer, since that individual will be most familiar with the procedural posture of the proceeding and the impact of the suspension upon the parties. Under the commenter's proposal, a lengthy suspension could translate into a day-for-day stay of the entire proceeding, even though alternative representation might be available much sooner. This could add unnecessary delay to licensing proceedings.

The commenter also suggests the establishment of an alternative appeals process in cases in which the Commission itself orders a suspension so that the Commission does not also function as the appellate body. Since the Commission acts as a collegial body in licensing proceedings, there will be no further administrative appeal of suspensions it orders. Judicial review would be available to a suspended representative. Therefore, the Commission believes an alternative appeals process is unnecessary.

One commenter suggests that the rule be amended to require the completion of an appellate hearing within 10 days of the imposition of the suspension or else the suspension should be revoked, not merely lifted. According to the commenter, this change is designed to prevent an automatic 10-day non-reviewable suspension. The Commission notes that it may not always be practical to complete a hearing within 10 days of the imposition of a suspension because the rule provides 10 days for filing an appeal. Since proposed § 2.713(c)(3) directs that a necessary hearing shall commence as soon as possible after the filing of an appeal, the Commission believes that the intent of the commenter is met.

However, after its own further review, the Commission has decided to broaden and revise the process for appealing suspensions in three respects. First, an appeal of a reprimand, censure, or suspension not exceeding 1 day is authorized. The proposed rule limited review to suspensions exceeding 1 day. The Commission believes that a right to appeal any sanction imposed pursuant to this section is desirable because, at least in the case of an attorney, an administratively unappealable sanction may saddle an individual with an irrevocable, and possibly unjustified, professional "black mark." In the District of Columbia, for example, an applicant for admission to the bar must state whether he or she has been suspended, reprimanded or censured as an attorney.

Second, the Commission has revised the proposed rule to delay the effectiveness of suspensions exceeding 1 day for a period of 72 hours from the time of the suspension order to permit the suspended individual to request a stay of the sanction from the reviewing tribunal pending appeal. A timely stay request will stay the imposition of the sanction until the reviewing tribunal rules on the motion. Ten days are provided for the Commission or Appeal Board, as appropriate, to rule on the motion. All time limits will be computed in accordance with 10 CFR 2.710. Responses to the stay request from other parties will not be entertained since they have no substantial interest in the disposition of the motion. In ruling on the motion, the reviewing tribunal will consider only the first two stay factors specified in 10 CFR 2.788(e) (whether the moving party has made a strong showing that it is likely to prevail on the merits and whether the party will be irreparably injured unless a stay is granted). The third and fourth factors (harm to other parties and the public interest) are excluded because each has little bearing on the proper disposition of the motion. This mechanism is provided in a new § 2.713(c)(4).

Finally, the Commission has modified the third sentence of proposed § 2.713(c)(3) to require an Atomic Safety and Licensing Appeal Board or the Commission, as appropriate, to consider each appeal on the merits. The modification will ensure that an appeal would not be declared moot if the suspension has been "served" prior to appellate consideration.

5. Referral to the state bar: One commenter recommends deletion of the provision of proposed § 2.713(c)(3) relating to notification of the appropriate state bar(s) if an attorney's suspension is upheld at the conclusion of the appeal, since no corresponding sanctions are imposed on non-lawyers and no pattern of attorney misconduct is cited. The Commission does not agree with this recommendation. Attorneys have an independent ethical obligation under the American Bar Association's Code of Professional Responsibility to refrain from engaging in undignified or discourteous conduct when appearing before a court or administrative tribunal (DR 7-106(c)(6)). Therefore, referral to the state bar(s) is appropriate in such cases.

However, proposed § 2.713(c)(3) implies that if an attorney receives a suspension exceeding 1 day and does not appeal, there is no referral to the state bar. The Commission has clarified the rule by requiring mandatory referral of attorneys whose suspensions exceed 1 day even when no appeal is taken. Referral should not depend upon whether an appeal is taken. Logic teaches that a suspended attorney who does not appeal may be more guilty than his peer who elects to appeal; therefore, both attorneys should be referred to the state bar if the suspension exceeds 1 day.

Pursuant to section 161(p) of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552, 553 and 553(b) of Title 5 of the United States Code, the following amendments to Title 10, Chapter 1, Code of Federal Regulations, Part 2 are published as a document subject to codification, to be effective on November 21, 1980.

45 FR 73465
Published 11/5/80
Effective 11/5/80

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10 CFR Part 2

Rules of Practice for Domestic Licensing Proceedings

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Commission is amending its rules of practice to conform the time permitted under 10 CFR 2.206(c) and 2.786(a) with its revised internal operating procedures which provide that the Commissioners have ten (10) working days to review the decision of the appropriate Office Director or of the Appeal Board and the advice of the General Counsel.

EFFECTIVE DATE: November 5, 1980.

FOR FURTHER INFORMATION CONTACT: Mark E. Chopko, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, 202/634-3224.

SUPPLEMENTARY INFORMATION: NRC regulations provide that the Commission may decide to review, on its own motion, a decision of the Appeal Board within thirty (30) days of the decision or after a petition for review is filed, whichever is later. 10 CFR 2.786(a), *as amended* 45 FR 45890 (July 8, 1980). In addition, § 2.206(c) provides that the Commission may decide to review a Director's decision within twenty (20) days of the decision. In both instances the time had been divided between review of the matter by the Office of the General Counsel in order to advise the Commissioners on a proposed course of action and consideration of the matter by the Commission. The Commission has recently adopted a revised set of internal operating procedures that now would provide ten (10) working days for Commissioner action. In order both to provide for adequate review in the Office of the General Counsel and to provide sufficient time for Commission consideration in conformance with the new operating procedures, the Commission has decided to amend its rules to add additional time for consideration of such decisions.

Section 2.786(a) will be amended to provide forty (40), instead of the existing thirty (30), days for Commission consideration of Appeal Board decisions on its own motion. This change does not affect the rest of § 2.786(a) including the recent amendment. 45 FR 45890. In addition, § 2.206(c)(1) will be amended to provide twenty-five (25), instead of the existing twenty (20), days for Commission consideration of a Director's decision.

Because this amendment relates solely to matters of agency procedure, notice of proposed rulemaking and public procedure thereon are not required by section 553 of Title 5 of the United States Code and shall be omitted from this proceeding. As rules applying only to internal agency procedure, these final rules will be effective November 5, 1980.

Accordingly, pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendment to Title 10, Chapter I, Code of Federal Regulations, Part 2, is published as a document subject to codification.

45 FR 74693
Published 11/12/80
Effective 11/28/80

Licensing Requirements for the Storage of Spent Fuel in an Independent Fuel Spent Storage Installation

See Part 72 Statements of Consideration

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46 FR 12192
Published 2/13/81
Effective 3/16/81

10 CFR Part 2

Rules of Practice for Domestic Licensing Proceedings; Administrative Appellate Briefs

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Commission is adding a new subsection to its rules of practice to limit the length of administrative appellate briefs to 70 pages.

EFFECTIVE DATE: March 16, 1981.

FOR FURTHER INFORMATION CONTACT: Alan S. Rosenthal, Chairman, Atomic Safety and Licensing Appeal Panel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone 301-492-7662.

SUPPLEMENTARY INFORMATION: The Commission's Rules of Practice do not now impose a limitation on the length of briefs filed on appeals from initial decisions. Section IX(d)(2) of Appendix A to those Rules (10 CFR Part 2) acknowledges that fact but then goes on to state that "in most cases the issues raised by the exceptions should be susceptible of full treatment in a brief which does not exeed 70 pages." That guidance had generally followed the rule applied in courts of appeals. In this connection, Rule 28(g) of the Federal Rules of Appellate Procedure now provides that "[e]xcept by permission of the court, or as specified by local rule of the court of appeals, principal briefs shall not exceed 50 pages * * * exclusive of pages containing the table of contents, tables of citations and any addendum containing statutes, rules, regulations, etc." Until amendment in 1979, that rule provided a 70-page limit and at least one court, the District of Columbia Circuit, has seen fit to increase the limitation to 70 pages. *See* D.C. Circuit Local Rule 8(g).

Over the years, the Appendix A guideline has frequently been ignored. As a consequence, in September 1978, the Appeal Board put the Bar "on notice * * * that, unless there is a greater general effort to adhere to the Section IX(d)(2) guideline, it likely will be considered necessary to convert that guideline into a limitation." *Public Service Co. of Oklahoma* (Black Fox Station, Units 1 and 2), ALAB-498, 8 NRC 315, 316 (1978). Despite this admonition, the Board still receives excessively long briefs from time to time.

In these circumstances, the Commission has accepted the Appeal Panel's recommendation to convert the Section IX(d)(2) "guidance" into a limitation akin to that enforced by the District of Columbia Circuit. This would not absolutely preclude, of course, briefs in excess of 70 pages. What it would mean is that, before filing such a brief, the litigant would be required to seek the Appeal Board's permission. In granting that permission where there appeared to be sufficient cause to do so, the Appeal Board would be free to set a specific new page limitation. For example, although the litigant might seek to file a 130-page brief, the Appeal Board might decide to allow a brief of 90 pages.

Section 2.762 will be amended to add a new subsection (e) containing the page limitation on appellate briefs. The existing subsection (e) will be redesignated subsection (f). Part 2, Appendix A, section IX(d)(2) will be modified to conform to this amendment.

Because this amendment relates solely to matters of agency procedure, notice of proposed rulemaking and public procedure thereon are not required by section 553 of Title 5 of the United States Code and shall be omitted from this proceeding. These final rules will become effective for all appellate briefs filed thirty days after publication in the **Federal Register**.

Accordingly, pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendment to Title 10, Chapter I, Code of Federal Regulations, Part 2, is published as a document subject to codification.

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46 FR 13681

Published 2/24/81

Effective 2/24/81

10 CFR Part 2

Domestic Licensing Proceedings; Procedural Assistance Program

AGENCY: Nuclear Regulatory Commission.

ACTION: Final Rules; Suspension of certain provisions.

SUMMARY: The Commission suspends immediately the effectiveness of 10 CFR 2.712(f) and 2.750(c), concerning procedural assistance to non-applicant parties in domestic licensing proceedings. This suspension is based on a December 3, 1980, decision of the Comptroller General (No. B-200585) that found unlawful the use of funds appropriated under Pub. L. 96–367 (FY 1981 Appropriations Act) for the provision of free transcripts to and copying and service of written submissions of non-applicant parties in these proceedings. The Commission may consider a revision of its transcript program at a future date.

EFFECTIVE DATE: February 24, 1981.

FOR FURTHER INFORMATION CONTACT: Martha A. Torgow, Attorney, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, 202/634–1465.

SUPPLEMENTARY INFORMATION: On July 25, 1980, the Commission published a final rule to implement a pilot program of procedural assistance in domestic licensing proceedings, except for antitrust proceedings, to parties other than the applicant by (1) providing a transcript without charge and (2) copying and serving certain written submissions on request. 10 CFR 2.750(c), 2.712(f), 45 FR 49535. In addition, the NRC reduced the number of copies required to be filed by any party with the Commission from 20 to 2. 10 CFR 2.708(d)(2), *supra*. The Commission had begun to implement that program in its licensing proceedings.

The Comptroller General was requested to review this program and determine whether it was lawful under Section 502 of the Energy and Water Development Appropriations Act for FY 1981, Pub. L. 96–367. That section states that FY 1981 funds may not "be used to pay the expenses of, or otherwise compensate, parties intervening in regulatory or adjudicatory proceedings funded in this Act." On December 3, 1980, the Comptroller General concluded that the first two elements of the program (free transcripts and free copying and service for non-applicant parties) could not be funded from moneys available under that Act, but that the third element (reduction of copies for all parties) could. Opinion No. B–200585. The Comptroller General reasoned that provision of transcripts and free copying and service were litigation expenses that would inevitably have been paid by the non-applicant party and that the assistance program transferred the expense to the NRC to be paid out of appropriated funds. However, a reduction in the number of copies of papers required to be filed did not compensate intervening parties, but merely eliminated a cost for all parties. On December 4, Chairman Ahearne ordered an immediate suspension of the NRC's procedural assistance program on transcripts and copying and service, pending further direction from the Commission.

This notice announces the formal suspension of the transcript and copying and service portions of the program, 10 CFR 2.750(c) and 2.712(f). Because implementation of these portions of the program through appropriations under the FY 1981 Appropriations Act has been found unlawful by the Comptroller General and thus would not be in the public interest, good cause exists for making this suspension effective without prior notice and comment and upon publication. The Commission may at some future time revise its program of free transcripts and will consider any comments filed on the suspension and proposals for future action which are filed with the Secretary of the Commission within 30 days of publication of this notice.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and Sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 2, are published as a document subject to codification.

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46 FR 13971

Published 2/25/81

Effective 3/27/81

Disposal of High-Level Radioactive Wastes in Geologic Repositories; Licensing Procedures

See Part 60 Statements of Consideration

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46 FR 22358

Published 4/17/81

Effective 4/17/81

10 CFR Part 2

ACRS Participation in NRC Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Commission is amending its Rules of Practice to provide procedures for participation by the Advisory Committee on Reactor Safeguards in NRC rulemaking activities.

The rule establishes procedures for definitive Commission action on recommendations by the ACRS that the Commission initiate rulemaking in a particular area. The rule also provides that the NRC Staff will give the ACRS an opportunity to provide advice and

identify issues when the Staff develops rules involving nuclear safety matters.

EFFECTIVE DATE: April 17, 1981.

FOR FURTHER INFORMATION CONTACT: Patricia R. Davis, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, 202-634-3224.

SUPPLEMENTARY INFORMATION: The President's Commission on the Accident at Three Mile Island recommended that the Advisory Committee on Reactor Safeguards (ACRS) become more involved in NRC rulemaking activities. This rule is consistent with the President's Commission's recommendation.

Because this amendment relates solely to matters of agency procedure, notice of proposed rulemaking and public procedure thereon are not required by section 553 of Title 5 of the United States Code and shall be omitted from this proceeding. As a rule applying only to internal agency procedure, this final rule shall be effective upon publication in the **Federal Register**.

Accordingly, pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendment to Title 10, Chapter I, Code of Federal Regulations, Part 2, is published as a document subject to codification.

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46 FR 28627
Published 5/28/81
Effective 5/28/81

10 CFR Part 2

Commission Review Procedures for Power Reactor Operating Licenses; Immediate Effectiveness Rule

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission hereby amends its review procedures for Licensing Board decisions granting nuclear power reactor operating license applications by requiring direct Commission review of those decisions to determine whether their effectiveness should be delayed pending normal agency appellate review. The amendment eliminates the Atomic Safety and Licensing Appeal Board review directed by Appendix B to Part 2 of the Commission's rules of practice. The amendment is intended to reduce the length of time between a Licensing Board decision permitting fuel loading and low-power testing or full-power operation and the Commission's decision on whether to permit the Licensing Board's decision to become effective.

EFFECTIVE DATE: May 28, 1981.

FOR FURTHER INFORMATION CONTACT: Martin G. Malsch, Esq., Deputy General Counsel, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (202-634-1465).

SUPPLEMENTARY INFORMATION: Appendix B to Part 2 was adopted some one-and-one-half years ago as an interim response to the Three Mile Island (TMI) accident in order to increase Commission supervision of adjudicatory licensing decisions involving power reactors. Under Appendix B, an initial decision by an Atomic Safety and Licensing Board favoring grant of a nuclear power reactor construction permit or operating license did not become effective until both the Atomic Safety and Licensing Appeal Board and the Commission had reviewed that decision and decided whether it should become effective. The review process contained in Appendix B nominally postponed the issuance of licenses for close to three months beyond a favorable Licensing Board decision.

Following the Three Mile Island accident, the Commission reassigned most of the staff who had been reviewing applications seeking authorization to construct or operate nuclear power reactors to other tasks, such as investigating the causes of the accident and developing new regulations based on the lessons learned. As a direct result of these reassignments construction of a number of plants will be finished prior to any effective decision by the Commission on the issuance of an operating license. On April 3, 1981, the Commission published in the **Federal Register** proposed alternative modifications of Appendix B designed to expedite the review process. 46 FR 20215. Two alternatives were set out for public comment: Option A, which retained a period of deferred effectiveness pending expedited Commission review of favorable Licensing Board decisions; and Option B, which would grant immediate effectiveness to favorable Licensing Board decisions while retaining the Appeal Board and Commission review process of Appendix B. The alternatives were designed to reduce or eliminate the delay between completion of construction and issuance of an operating license following a favorable Licensing Board decision.

Approximately 90 comments on the proposed rule were received from interested individuals and organizations, divided along two distinct lines which may be characterized as intervenor- and nuclear industry-oriented positions. Intervenors, over two-thirds of the commenters, favored retention of Appendix B, generally citing concerns that elimination of Appendix B reviews would provide less assurance that TMI-related policy concerns would be included in decisions. Nuclear industry commenters, meanwhile, favored Option B of the proposed alternative modifications, generally citing the thoroughness of the review process before Appendix B takes hold. These commenters often stated a strong preference for full reinstatement of the immediate effectiveness rule. Several industry commenters also urged reinstatement of the immediate effectiveness rule for construction permits, a matter that is the subject of another, separate rulemaking.[1]

SECY 81-307, a brief analysis of the public comments, was prepared for the Commissioners by the Office of the General Counsel and, along with a copy of all comments received, is available for public inspection at the NRC Public Document Room, located at 1717 H Street, NW., Washington, D.C.

The Commission has reassessed its Appendix B process in light of the need for expedited decisions in a number of pending operating license cases. It has concluded that the full Appendix B reviews of operating license decisions are not necessary. Therefore, some changes to Appendix B are warranted in order to avoid unwarranted and expensive delays.

The commission has decided to adopt the proposed Option A. This decision is based upon a balancing of two competing factors: (1) The benefit of direct Commission consideration of nuclear power reactor operating licenses; and (2) the costs associated with postponing operation of completed plants.

This amendment does not compromise the Commission's commitment to the protection of public health and safety or to a fair hearing process. Thorough technical safety reviews of license applications by the NRC staff and the Advisory Committee on Reactor Safeguards, the availability of public hearings on license applications, and the Commission's inherent supervisory authority form the basis of the network of procedural safeguards intended to implement this commitment to a fair decision process and public health and safety. These are all unaffected by the instant rule change. When warranted, stays of effectiveness remain available pursuant to the standard procedure and criteria of 10 CFR 2.788. The Commission review provided for in this amendment will focus narrowly on significant policy issues. The Commission does not intend to review the entire record developed during the licensing proceeding.

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[1] See 45 FR 34279 (May 22, 1980).

Because these amendments relate solely to procedural matters and serve o relieve procedural restrictions on licensees, the Commission has determined to make them effective upon publication in the **Federal Register**.

Finally, the format of the rule has been revised to conform to **Federal Register** guidance on proper format, removing Appendix B and incorporating the Appendix B procedures, as amended, into 10 CFR 2.764.

Commissioner Ahearne's Dissenting Views

The Appendix B procedures were developed so that the Commission could decide issues for which no guidance had been given because the TMI-related reviews had not been completed. Modification of the Appendix B procedure for operating licenses is now appropriate because of the progress which the NRC has made in incorporating into its safety requirements lessons learned from review of the accident at Three Mile Island.[2]

For areas in which the Commission has provided clear guidance to the Boards, I believe that short Commission review is not necessary and serves only to provide the appearance of Commission involvement. For areas in which the Commission has not provided such guidance, a short review will not suffice for reaching a Commission conclusion and I expect a lengthy period to elapse between Board decision and Commission decision. Consequently, I find little real value in adopting a version of the Appendix B procedure which requires the Commission to formally grant the license based on a brief review. Although the Commission's addition of a provision allowing parties to comment is helpful because it should focus the Commission's attention on areas of concern, I still do not support Option A.

Since the Commission has addressed TMI-related requirements, I would have reinstated the immediate effectiveness of Licensing Board decisions for operating licenses. I continue to support a procedure which would provide the Commission an opportunity to examine a decision relatively soon after a decision is issued. This would allow the Commission to address any major misunderstanding of its guidance as well as to identify any substantial weaknesses in the Licensing and Appeal Boards' decisions.

Therefore, I would have adopted Option B which would have restored immediate effectiveness to Licensing Board decisions for operating licenses while retaining the Appeal Board and Commission stay review under current Appendix B procedures.

Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission hereby certifies that this rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. This rule affects the Commission's Rules of Practice and procedures by permitting expedition of the licensing process.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and section 553 of the United States Code, notice is hereby given of the adoption of the following amendments to 10 CFR Part 2.

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[2] The Commission itself provided guidance on TMI-related requirements for operating licenses (45 FR 41738 (June 20, 1980), 45 FR 85236 (Dec. 24, 1980)) and currently public comment is being requested on a proposed rule codifying those requirements (46 FR 26491 (May 13, 1981)).

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46 FR 30328

Published 6/8/81

Effective 6/8/81

10 CFR Part 2

Rules of Practice for Domestic Licensing Proceedings; Expediting the NRC Hearing Process

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission has adopted several amendments to its Rules of Practice to facilitate expedited conduct of its adjudicatory proceedings on applications to construct or operate nuclear power plants. These amendments authorize the licensing boards to make oral rulings on written motions during the course of a prehearing conference or a hearing, preclude parties from filing responses to objections to a prehearing order unless the licensing board so directs, revise the schedule for filing proposed findings of fact and conclusions of law, and permit summary disposition motions to be filed at any time during the course of the proceeding.

EFFECTIVE DATE: June 8, 1981.

FOR FURTHER INFORMATION CONTACT: Trip Rothschild, Esq., Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (202–634–1465).

SUPPLEMENTAL INFORMATION: On March 17, 1981 the Commission published in the **Federal Register** (46 FR 17216) a Notice of Proposed Rulemaking soliciting public comments on six proposed changes to the Commission's Rules of Practice, 10 CFR Part 2. The principal purpose of the proposed amendments was to shorten the hearing process on applications to construct or operate a nuclear power plant, without reducing the overall quality or fairness of NRC adjudicatory proceedings. In response the Commission received more than 600 comments. The comments are set forth and analyzed in SECY 81–252, a publicly available memorandum from the Commission's General Counsel to the Commission and, therefore, only a brief summary of the more significant comments is contained in this Notice.

The Commission also sought comment on a proposed model hearing schedule which would serve as a guideline for NRC's administrative judges. The Commission is still deliberating on the proposed schedule and, therefore, a model schedule is not set forth in this notice.

1. Eliminate Discovery Against the NRC Staff

Currently, parties to NRC licensing proceedings may engage in formal discovery against the NRC staff. The Commission sought comment on a proposed rule which would eliminate formal discovery against the staff. Most of the commenters opposed the proposal, arguing that their participation in a proceeding would be severely impeded if they could not obtain relevant information from the NRC staff through formal discovery prior to the commencement of the hearing or that elimination of discovery against the staff might lengthen the licensing process. A majority of the Commission does not support the proposed rule and it has not been adopted. However, the Commission has under consideration a different proposal which would limit the number of interrogatories that a party may file against another party in an NRC adjudicatory proceeding. Public comment would be sought in a future rulemaking proceeding on any such proposal.

2. Permit the Licensing Boards to Rule Orally on Written Motions

Under 10 CFR 2.730(e), licensing boards are required to issue written orders on those motions submitted to them in writing. The Commission sought comment on a proposed rule which would permit the boards, where appropriate, to issue oral rulings addressing such motions during the course of a prehearing conference or hearing.

Many of the nuclear industry commenters supported the proposed rule change noting that it could expedite the hearing process by enhancing the ability of the licensing boards to rule promptly on motions pertaining to procedural matters. Several emphasized, however, that if oral rulings are permitted, a board must take care to fully spell out its reasoning.

Intervenors, on the other hand, opposed the rule change because of a concern that they would not promptly learn of oral rulings. Intervenors frequently limit their attendance at the hearings to the days when their contentions are being litigated, and do not have the resources to purchase transcripts. Intervenors asserted that without prompt notification they could miss filing deadlines imposed by the boards in oral rulings and the period for seeking reconsideration of a board's ruling could expire before they learned of the ruling.

After evaluating these comments, the Commission has adopted a rule which amends 10 CFR 2.730(e) to permit the boards to make oral rulings on written motions, but will require the board to ensure that the parties are promptly notified of the ruling. This will permit oral rulings where this could expedite the proceedings, or is otherwise appropriate, without prejudicing any party. Several mechanisms are available to notify absent parties of the ruling. The Board may notify the party by phone; it may direct one of the parties present to contact the absent party; or it may serve the transcript pages containing the order on all parties. The Commission encourages the boards at a minimum to serve the transcript pages. When the boards rule orally they are also directed to take special care to fully set forth the reasoning behind the decision.

3. Prohibit Motions to Reconsider Prehearing Orders

Under 10 CFR 2.751(d) and 2.752(c) parties other than the NRC staff may file, within five days after service of a board prehearing order, an objection to the order. Such an objection constitutes, in effect, a motion requesting the board to reconsider its ruling. The NRC staff has ten days after service of the order to request reconsideration. The Commission sought comment on a proposed rule which would preclude parties from filing requests for reconsideration of prehearing orders.

Virtually all commenters opposed the proposed rule change arguing that mistakes which could significantly affect the proceeding might be prevented if motions for reconsideration are not permitted. Moreover many commenters argued that the proposed rule would not result in significant time savings because such motions which are without merit can be promptly answered and denied, and the proceeding may continue while the motions for reconsideration are pending. It was further argued that it is unclear how the proposed change would save time, particularly in comparison with the time which would be required should the licensing board be reversed for an error which a party wished to but could not bring to the board's attention.

The Commission agrees with the commenters and therefore has not adopted the proposed rule. However, the Commission has adopted other changes to its regulations pertaining to objections to or motions for reconsideration of prehearing orders. The Commission has observed that objections or motions for reconsideration are not frequently granted. The Commission therefore is amending its regulations to take away the right of a party to file an answer to an objection or motion for reconsideration. Responses will only be permitted, if the licensing board so directs. This means that motions which on their face have little merit will be summarily dismissed by the board. Parties will be asked to respond only to those motions that a board believes may have some merit.

In addition, although the Commission's present rules do not so dictate, it is possible under the present practice for an objection or motion for reconsideration to have the effect of staying the effectiveness of the board's order until the board rules on the matter. The Commission has adopted an amendment to its regulations which provides that filing of an objection to or a motion for reconsideration does not stay the effectiveness of the prehearing order, unless the board for good cause shown determines that the decision should be stayed pending board action. Thus parties are to proceed with prehearing matters on admitted contentions, even though objections to or motions for reconsideration of the ruling admitting the contentions are pending before the board. This approach would be consistent with existing regulations pertaining to petitions for reconsideration of final board decisions, 10 CFR 2.771(c).

4. Permit Licensing Board Chairman to Rule on Prehearing Matters Without Consulting Other Board Members

Under 10 CFR 2.721(d) and 2.718, when a licensing board is not in session, the chairman of the board (who is always qualified in the conduct of administrative proceedings) is vested with the power to rule on procedural requests. This includes ruling on intervention petitions, contentions, motions for summary disposition requests to compel a party to respond to interrogatories, and requests for extention of time. However, in practice the board chairman does not rule alone on petitions for leave to intervene, contentions, or motions for summary disposition because the technical expertise of the administrative judges serving on the board who have scientific backgrounds is frequently essential in ruling on such motions. The Commission sought comment on a proposed rule which would permit the licensing board chairman to act alone on all prehearing matters. It would be within the discretion of the chairman to consult with the other administrative judges before taking action.

Few commenters supported this proposal. The commenters argued that it would be a serious error to allow the chairman to act alone in issuing substantive orders on prehearing matters, such as ruling on contentions and motions for summary disposition. On this point the commenters emphasized that prehearing orders set the framework for the hearing and therefore the technical administrative judges should contribute to the decision. Others commented that centralized decisionmaking may be appropriate in times of crisis, but is not necessary in licensing proceedings. Others argue that the proposal was inconsistent with Congress' intent in establishing three member panels to preside over NRC hearings.

Based upon the review of these comments, the Commission has decided not to amend 10 CFR 2.721 as proposed. The Commission believes that the present practice whereby all three board members participate in acting upon substantive prehearing orders should continue.

5. Eliminate the Right of the Applicant to File a Reply to Other Parties' Proposed Findings of Fact and Conclusions of Law

Under 10 CFR 2.754(c) unless otherwise directed by the board, the applicant must file its proposed findings of fact and conclusions of law within 20 days after the record is closed. The filings from the other parties, except for the NRC staff are due 30 days after the close of the record. Staff's filing must be filed by day forty. The applicant must file its reply to the other parties' submissions within ten days after service of the other parties' filings. The Commission sought comment on a proposed rule which would eliminate the right of the applicant to file a reply submittal.

A few commenters supported the proposed rule change arguing that the applicant should be given only one opportunity to set forth its views and that the licensing board is capable of making its findings without having a reply finding from the applicant. However, most commenters opposed the rule change. Because the applicant has the burden of proof in NRC initial licensing proceedings, many argued that fairness dictates the it should have the last word. It was also argued that the applicant's reply filing served a useful function because it focused on the disputes between the parties and permitted prompt resolution of issues by the board. Finally, many commenters noted that if the applicant wished to expedite the proceeding, it could waive the opportunity to file a reply pleading.

After reviewing these comments, the Commission has decided not to eliminate the right of the applicant to file a reply pleading. However, it has adopted amendments to 10 CFR 2.754 which alter the time limits for filing proposed findings of fact. Experience indicates that because of the complexity of NRC proceedings the applicant frequently is unable to file its proposed findings within the prescribed 20-day period and the Board must establish another filing schedule. The Commission therefore is modifying the schedule to make it more realistic. Under the new regulations the applicant's submission will be due thirty days after the record closes, the filing of other parties (except for the NRC staff) will be due 40 days after the record closes. The staff's pleading will be due 50 days after the record closes. The applicant's response will be due 5 days after the staff files its proposed findings, five days earlier than the ten days allowed under prior regulations. The Commission contemplates that staff would hand-deliver or air express its filing to the applicant to provide applicant a reasonable time to respond. Although boards are authorized to deviate from this suggested schedule, it is expected that absent special circumstances, including considerations of fairness, the board will not authorize use of a more extended filing schedule. In cases with few parties, and few contentions, the boards are encouraged to order use of a more compressed filing schedule.

6. Eliminate Requirement That Motions for Summary Disposition be Submitted no Later Than 45 Days Before the Commencement of the Hearing

Under 10 CFR 2.749(a) parties to proceedings must file any motions requesting summary disposition at least 45 days prior to the start of the hearing. The Commission sought comment on a proposed rule which would permit motions for summary disposition to be filed at any time. However, the board would be authorized to set appropriate time limits for the filing of such motions which would be tailored to fit the circumstances.

Although a few commenters favored the proposed change because it would provide greater flexibility in the use of these motions, most commenters opposed the proposed change. The major arguments advanced against the proposal are that if there is no genuine factual dispute which exists on a particular issue, a competent attorney should recognize that well before the hearing, and that late filed motions actually disrupt and delay the hearing. Commenters frequently noted that most motions for summary disposition are filed against intervenors, who generally have limited resources. Because responding to summary disposition motions requires a substantial effort, if motions are filed just before the hearing or during the hearing itself, intervenors will be required to divert resources from ongoing efforts to prepare testimony or to prepare for cross-examination. Late filed motions similarly distract the other parties to the proceeding as well as the board which must rule on the motion. Several commenters suggested that if the boards are given the discretion to permit motions for summary disposition to be filed less than 45 days prior to the commencement of the hearing, they should be directed to reject summarily motions which would unduly divert parties' resources away from the hearing.

After evaluating these comments, the Commission has adopted a rule which provides that motions for summary disposition may be filed at any time, but that the boards are to reject motions filed right before the hearing or during the hearing itself where response to such motions would require the other parties or the board to divert substantial resources from the hearing. Boards are directed in each case at an early date to set forth an appropriate scheduled for filing motions for summary disposition. This approach should provide the board maximum flexibility in setting a schedule for the filing of such motions, but will discourage filing of motions right before the hearing or during the hearing itself.

The Commission has also adopted one other minor amendment to the regulations. In 1980 the Commission adopted an amendment to 10 CFR 2.749(a) which provides that a party may file an answer in support of a motion for summary disposition, as well as in opposition to such a motion. The Commission also revised the regulations to permit the party opposing the motion for summary disposition to file a supplemental response which addresses any new matters raised in answers supporting the motion. The Commission directed its boards to establish expeditious time limits on a case-by-case basis for the filing of any response to supporting statements consistent with the requirements of fairness.

The Commission has amended the regulations to provide for a ten-day response period rather than having the boards establish the time for response on a case-by-case basis. Unlike the other amendments addressed in this Notice, the Commission did not seek public comment on this minor change. The Commission has determined that public comment is not required because the amendment is procedural in nature.

Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission hereby certifies that this rule will not have a significant economic impact on a substantial number of small entities. This rule affects the Commission's rules of practice and procedures by permitting expedition of the licensing process.

Because the amendments are related only to matters of procedure, the Commission is making the amendments effective upon publication in the **Federal Register**. Accordingly, pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter 1, Code of Federal Regulations, Part 2, are published as a document subject to codification to be effective upon publication in the **Federal Register**:

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46 FR 34794

Published 7/6/81

Effective 7/6/81

10 CFR Part 2

Rules of Practice for Domestic Licensing Proceedings

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Commission is amending its regulation on the authority of the Secretary to rule on procedural matters to permit the Secretary to refer pleadings improperly directed to the Commission's attention to the appropriate adjudicatory board.

EFFECTIVE DATE: July 6, 1981.

FOR FURTHER INFORMATION CONTACT: Mark E. Chopko, Attorney, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, 202-634-3224.

SUPPLEMENTARY INFORMATION: In the past several years, parties to proceedings before an Atomic Safety and Licensing Board have filed appeals or other pleadings on various subjects directly with the Commission rather than the cognizant Atomic Safety and Licensing Appeal Board. These pleadings have been referred to the Appeal Board by the Commission. *See, e.g., Pennsylvania Power and Light Co.* (Susquehanna Steam Electric Station, Units 1 and 2), CLI–80–17, 11 NRC 678 (1980). Presently, the Commission's Rules of Practice do not authorize the Secretary to direct referral of such misfiled pleadings under 10 CFR 2.772. Therefore, unless the pleadings are simultaneously filed with the Appeal Board, formal action by the Commission is required. Similarly, parties may file pleadings and motions with the Commission instead of the appropriate Licensing Board in cases (such as some enforcement actions) where the Commission must empanel a board to hear the case.

Scheduling such matters for Commission meetings frequently causes delay in taking formal action. To expedite this process and to conserve the Commission time that is now devoted to review and approval of these matters, the Commission has decided to amend 10 CFR 2.772, concerning the Secretary's authority to rule on procedural matters, to provide that such pleadings may be referred directly by order of the Secretary. The Secretary will act upon the advice of the Office of the General Counsel and after consultation with the Commissioners' offices. The Commission expects that this review of the pleadings will identify matters of extraordinary importance or beyond a Board's authority that the Commission must address directly.

Because the rule change concerns solely a matter of internal agency procedure and does not change any substantive practice, notice of proposed rulemaking and public procedure thereon are not required and, for the same reason, the final rule is effective July 6, 1981. Accordingly, pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendment to Title 10, Chapter I, Code of Federal Regulations, Part 2, is published as a document subject to codification.

46 FR 35486
Published 7/9/81
Effective 7/9/81

Expedited Procedure for Handling Certain Petitions for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its rules of practices for processing petitions for rulemaking to include provisions for handling certain petitions for rulemaking with an expedited procedure that begins with publication of a notice of proposed rulemaking. This procedure will reduce the time required to respond to selected petitions and eliminate the need to publish in every case a notice of receipt of petition for rulemaking.

EFFECTIVE DATE: July 9, 1981.

FOR FURTHER INFORMATION CONTACT: J. M. Felton, Director, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Telephone 301–492–7211.

SUPPLEMENTARY INFORMATION: The Commission's current practice, as codified in 10 CFR 2.802(e), is to notice in the **Federal Register** the receipt of all petitions for rulemaking that meet the criteria of 10 CFR 2.802(c) and to invite public comment at that time. The NRC staff then reviews the merits of the petition in light of the public comments received.

This is an appropriate procedure for most petitions for rulemaking. The public is given an early opportunity to support or oppose the petitioner's proposals, and the staff is given some indication of the extent of public interest in the petition. This comment period is particularly important when rulemaking is denied, since no further comment period will be available. If all or part of the petition is granted, further public comment may be sought if a proposed rule is developed in response to the petition.

In certain cases, however, this initial comment period is unnecessary. The Commission receives, with some frequency, petitions which request minor rule amendments and which are obviously meritorious. An example might be a petition to establish a definite period for licensee retention of certain records that need not be retained indefinitely. Another example might be a petition to clarify an apparent ambiguity created by reading various parts of NRC's regulations in tandem and the resolution requires no substantial change in policy. In such cases it may be clear that the amendment is necessary and desirable and should be accomplished with a minimum of delay and expenditure of staff resources. This can be done by providing for preliminary staff review of all petitions for rulemaking to separate those which meet appropriate criteria for early action.

Use of the expedited procedure in any particular case is a matter of Commission and staff discretion. However, in general, petitions which are likely to be considered for expedited treatment, in addition to the examples described above, include those which: propose amendments involving interpretive rules, rules of agency organization, procedure or practice; propose amendments to substantive Commission regulations which are corrective or of a minor or nonpolicy nature and do not substantially modify existing regulations; propose amendments which grant or recognize exemptions or relieve restrictions from Commission regulations; or, propose amendments already under consideration in ongoing rulemaking proceedings. Petitions which are not likely to be suitable for expedited consideration include those which would: require preparation of an Environmental Impact Statement or otherwise have a significant impact on NRC staff and resource commitments; impose new or increased reporting or recordkeeping requirements subject to clearance by the Office of Management and Budget under the Paperwork Reduction Act, Pub. L. 96–511; or, have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, Pub. L. 96–354.

For petitions considered for expedited treatment, the staff would proceed immediately to develop a proposed rule rather than await public comment on the petition itself. (For petitions of this kind, it is often the case that little or no public comment is received in any event.) All other petitions, of course, would continue to be published for early comment.

One minor change in the Commission's rules is necessary to implement this "fast-track" procedure. Paragraph (e) of 10 CFR 2.802 currently provides that, by means of a notice of docketing published in the **Federal Register**, public comment will be invited upon all petitions for rulemaking. The amendment provides that public comment may be invited upon the petition itself, or, in appropriate cases, may be requested for the first time upon publication of a proposed rule developed in response to the petition. Each petitioner will be notified directly as to which procedure is being followed in his or her case.

Because this amendment is not substantive and relates only to matters of agency procedure, notice of proposed rulemaking and public procedure thereon is unnecessary, and the amendment is effective without the customary 30 days notice.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and Sections 552 and 553 of title 5 of the United States Code, the following amendment to Title 10, Chapter I, Code of Federal Regulations, Part 2 is published as a document subject to codification.

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46 FR 47764
Published 9/30/81
Effective 9/23/81

10 CFR Part 2

Commission Review Procedures for Power Reactor Operating Licenses; Immediate Effectiveness Rule

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its recently adopted final rule on review procedures for Licensing Board decisions granting power reactor operating license applications, 46 FR 28627 (May 28, 1981). The Commission will retain to itself the decision as to whether or not a plant will be allowed to go into commercial operation, i.e. receive a full power license. However, the rule is being modified so as to delete the requirement that the Commission conduct an effectiveness review prior to fuel loading and low-power testing, and to make other clarifying changes. The reconsideration is prompted by Commission experience in reviewing several recent cases.

EFFECTIVE DATE: September 23, 1981.

FOR FURTHER INFORMATION CONTACT: Martin G. Malsch, Deputy General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555 (telephone: 202–634–1465).

SUPPLEMENTARY INFORMATION: In the aftermath of the accident at Three Mile Island, the Nuclear Regulatory Commission had suspended in part its so-called immediate effectiveness rule which permitted favorable Licensing Board decisions to go into effect notwithstanding the filing of administrative appeals, and imposed in its stead a special *sua sponte* Commission review process designed to assure that no decision authorizing issuance of a nuclear power reactor construction permit or operating license could become effective without prior Commission review. *See* 44 FR 58559 (October 10, 1979), 44 FR 65049 (November 9, 1979), 10 CFR Part 2, Appendix B (1980 ed.). On May 28, 1981, after consideration of numerous public comments in response to a notice of proposed rulemaking, 46 FR 20215 (April 3, 1981), the Commission replaced the special review procedure for operating licenses with new procedures designed to reduce unnecessary delays. 46 FR 28627 (May 28, 1981). A more complete explanation of the background, purpose, and effect of this rulemaking proceeding can be found in the notices of proposed and final rulemaking cited above. The new procedures still called for Commission review prior to issuance of any power reactor operating license, including a license for fuel loading and low power testing.

The Commission has reconsidered whether it must, as a policy matter, complete a review of favorable Licensing Board decisions prior to fuel loading and low power testing (up to 5 percent of rated power), and commercial operation (full power). The Commission has concluded that it must retain the authorization of the full power license in order to fulfill the responsibilities of the Commission. These are the fundamental licenses granted by the NRC. However, the Commission has concluded that such review is not necessary for fuel loading and low power testing. First such activities involve minimal risk to the public health and safety, in view of the limited power level and correspondingly limited amounts of fission products and decay heat, and greater time available to take any necessary corrective action in the event of an accident.

Second, in operating license cases since the Three Mile Island accident the Commission has generally conducted its effectiveness review on a two-stage basis, first reviewing a fuel loading and low power testing license and then reviewing a full power license. Commission experience has been that in no case has fuel loading and low power testing prejudiced the later full power decision.

Accordingly, the Commission is reconsidering the review procedures adopted on May 28, 1981 so as to, in effect, reinstate the immediate effectiveness rule to the limited extent of allowing nuclear power reactor fuel loading and low power (up to 5 percent of rated power) testing based on favorable Licensing Board decisions notwithstanding the filing of exceptions. The Commission will retain the power to authorized full power operation. Also, language has been added to 10 CFR 2.764 to preserve Commission *sua sponte* authority to, in effect, suspend the immediate effectiveness rule in any case where special circumstances indicate this to be sound policy. This *sua sponte* authority is not intended to serve as a parallel avenue for parties to seek and obtain stays. 10 CFR 2.788 should be used for this purpose.

Thus, in a typical case the Director of Nuclear Reactor Regulation may issue a license within ten days from the date of issuance of a full power decision,[1] unless a stay motion was granted under 10 CFR 2.788, or there were some uncontested matters still requiring resolution. The same would hold true for low power decisions.

Finally, the new review procedures, as well as the old procedures adopted in 1979, are intended to apply only to nuclear power reactors, and the new rule has been clarified to this effect.

These rule changes will be applied prospectively, i.e., to initial decisions issued after the rule changes' effective date. Thus, they will not apply to cases like Diablo Canyon where the decisions were issued before the effective date, and the rules, as amended on May 28, 1981, will still apply to such cases. Also, these rule changes will not apply to the Three Mile Island Unit 1 restart cases where special effectiveness procedures are in effect or to any other case which involves extraordinary circumstances.

The review procedures addressed in this rulemaking apply only to contested operating license cases. Uncontested operating license cases are governed by a policy statement, issued in October 1979, 44 FR 58559 (October 10, 1979), which prohibited NRC staff from issuing any power reactor operating license without prior Commission review. The Commission, in this same issue of the **Federal Register**, is conforming its practice in uncontested cases to the rule changes herein by revising the earlier policy statement so as to delegate to the staff the authority to permit fuel loading and low power testing in uncontested cases without prior Commission review. *See* Table of Contents for this issue of the **Federal Register**.

The new rule is a variation on one of the proposals submitted for comment in the Commission's recent rulemaking proceeding. Indeed, many commenters urged the full reinstatement of the immediate effectiveness rule. Thus the new rule raises no policy considerations that were not raised in the earlier rulemaking. The change is also procedural in nature. It does not in any way modify any of the Commission's substantive standards for issuance of nuclear power reactor operating licenses and it has no significant effect on the participatory rights of parties to contested operating license hearings. The procedure and standards for parties to seek and obtain stays of adjudicatory decisions are set forth in 10 CFR 2.788 and remain unchanged and fully in effect. For these reasons the Commission believes that further notice of proposed rulemaking and public comment is unnecessary.

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[1] The Commission expects that in the usual case of a favorable full power Licensing Board decision the Director of Nuclear Reactor Regulation would be able to issue the license using the format of a full power license but with the special added condition that operation beyond 5 percent of rated power is not allowed. This eliminates the need to prepare two separate license documents, one for low power and one for full power, but has no substantive effect on the activities authorized.

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission hereby certifies that these rule changes will not have a significant economic impact on a substantial number of small entities. These rule changes would affect the Commission's procedures by permitting expedition of the licensing process. Because these rule changes relate solely to procedural matters and serve to remove procedural restrictions on licensees, the Commission has determined to make them effective upon publication in the **Federal Register**. Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of Title 5 of the United States Code, notice is hereby given that the following amendments to 10 CFR Part 2 are published as a document subject to codification.

46 FR 51718
Published 10/22/81
Effective 10/22/81 for Sections 2.744(e), 2.790(d)(1), 73.2(jj) and (ll), and 73.21(a), (b) and (c)(1). All remaining sections will be effective on 1/20/82.

Protection of Unclassified Safeguards Information

See Part 73 Statements of Consideration

46 FR 55083
Published 11/6/81
Effective 11/6/81

10 CFR Part 2

Use of Administrative Law Judges in Antitrust Proceedings

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Commission is amending its regulations to provide specifically for the appointment of Administative Law Judges to rule on requests for hearing and/or petitions to intervene and to preside in proceedings to consider the antitrust aspects of construction permit and license applications for nuclear power reactors and other production and utilization facilities. The Commission believes that the new hearing procedures will reduce the cost of conducting administrative antitrust proceedings and result in a more efficient use of personnel resources.

EFFECTIVE DATE: November 6, 1981.

FOR FURTHER INFORMATION CONTACT: B. Paul Cotter, Jr., Chief Administrative Judge, Atomic Safety and Licensing Board Panel, Washington, D.C. 20555, Telephone: (301) 492-7814.

SUPPLEMENTARY INFORMATION: Pursuant to Section 105 of the Atomic Energy Act of 1954, as amended, the Commission must ensure that licenses it grants for nuclear power reactors and other production and utilization facilities do not create or maintain a situation inconsistent with the antitrust laws. Section 105 contemplates that a hearing on the antitrust aspects of a license application for a production or utilization facility, including a nuclear power reactor, may be necessary.

Pursuant to Section 105 of the Act, the Commission may hold antitrust proceedings when it finds that the public interest requires a hearing to consider the antitrust aspects of an application. A notice of hearing is issued pursuant to 10 CFR 2.104 of the Commission's rules of practice which specifies the kind of information which must be included in the notice. However, § 2.104(d) does not require the notice to state who will conduct the hearing on antitrust matters.

Frequently, antitrust proceedings result from requests for hearing filed by interested persons. The appointment of a presiding officer to rule on such requests and to conduct any subsequent proceedings is governed by 10 CFR 2.105(e) of the Commission's Rules. This provision now states that the Commission itself or a three-member atomic safety and licensing board appointed pursuant to section 191 of the Act will perform these functions.

The Commission believes that many antitrust proceedings can be conducted as well by a single Administrative Law Judge as by a three-member board. Because antitrust hearings are usually lengthy, substantial savings in personnel would result if a single hearing officer rather than a three-member board is assigned to conduct them. In its recent review of the hearing process, the Commission determined that the assignment of Administrative Law Judges to antitrust proceedings would free substantial resources of the Atomic Safety and Licensing Board Panel. Members of the Panel who thus become available can be assigned to operating license proceedings for nuclear power reactors which the Commission must complete without delay. See the Commission's Statement of Policy on the Conduct of Licensing Proceedings of May 20, 1981, 46 FR 28533, May 27, 1981. Consequently, the Commission is amending 10 CFR 2.104(d) and 2.105(e) and portions of section X of Appendix A to 10 CFR Part 2 to provide that antitrust matters may be assigned to an Administrative Law Judge instead of a three-member board.

Because the amendments relate solely to matters of internal agency procedure and do not change any substantive practice, notice of proposed rulemaking and public procedure thereon are not required by 5 U.S.C. 553, and, for the same reason, the Commission has found that good cause exists for making the amendments effective upon publication in the **Federal Register.**

Regulatory Flexibility Act Statement

This final rule is not subject to the provisions of the Regulatory Flexibility Act, Pub. L. 96-354, 94 Stat. 1164. The Commission has determined pursuant to 5 U.S.C. 553 that a notice of proposed rulemaking need not be issued and that the rule may be promulgated in final form and become effective on the date of publication in the **Federal Register.**

Paperwork Reduction Act Statement

The provisions of the Paperwork Reduction Act of 1980, Pub. L. 96-511, 94 Stat. 2812, are not applicable to this final rule because the final rule does not contain any new or amended requirements for recordkeeping, reporting, plans or procedures, applications, or any other type of information collection.

PART 2—RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS

For the reasons set out in the preamble and pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552 and 553, the following amendments to Title 10, Chapter 1, Code of Federal Regulations, Part 2, are published as a document subject to codification.

46 FR 58279
Published 12/1/81
Effective 12/1/81

10 CFR Part 2

Expediting the NRC Hearing Process

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission has adopted amendments to its Rules of Practice to facilitate expedited conduct of its adjudicatory proceedings. These amendments permit the presiding officer to require oral answers to motions to compel responses to discovery requests and to require service of documents by express mail.

EFFECTIVE DATE: December 1, 1981.

FOR FURTHER INFORMATION CONTACT: Trip Rothschild, Esq., Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Telephone: (202) 634–1465.

SUPPLEMENTARY INFORMATION: On June 8, 1981, the Commission published in the Federal Register (46 FR 30349) a notice of proposed rulemaking soliciting public comments on four proposed changes to its Rules of Practice, 10 CFR Part 2. The changes would (1) raise the threshold for the admission of contentions; (2) limit the number of interrogatories that a party could serve on another party, unless consent to file additional interrogatories is obtained from the presiding officer; (3) authorize the presiding officer to require that responses to motions to compel answers to discovery requests be made orally in a conference telephone call or at a prehearing conference, rather than in writing, and (4) permit the presiding officer to require service of documents by express mail. The Commission received sixty-one comments. After reviewing the comments, the Commission has adopted the proposals relating to oral responses to motions to compel answers to discovery requests, and service of documents by express mail. The Commission has adopted these proposals because they provide the presiding officer with additional means to expedite proceedings, where timely completion of the proceeding is important. The other two proposals will be addressed in subsequent Federal Register notices.

1. Oral Responses to Motions To Compel Responses to Discovery Requests

Under the Commission's current regulations, 10 CFR 2.730(c), parties may file responses to motions to compel answers to discovery requests. To expedite NRC proceedings, the Commission proposed amendments to its regulations which would provide the presiding officer with the discretion to order that the responses be made orally in a conference telephone call or other prehearing conference rather than in writing.

The nuclear industry commenters generally supported the proposal; intervenors generally opposed it. Both industry and intervenor commenters thought the proposed rule to be deficient because it did not provide that a written record of the arugment would be prepared. Some commenters suggested that the parties be permitted to provide the presiding officer with written summaries of their position following oral argument. Others suggested that a transcriber be made a party to the call. The commenters were concerned that, without a written record, opportunities to appeal the decision of the board could be prejudiced.

Some commenters suggested that the presiding officer should require oral responses only in those proceedings where plant construction is projected to be finished before the licensing process is completed. These commenters argued that use of oral responses should not be a routine procedure, but only used when time is of the essence.

Several commenters also suggested that if the proposed rule is adopted, it should be revised to provide that parties be given a minimum preparation time following the filing of a motion to compel before oral argument is held on the motion.

Commenters also asserted that the costs of conference telephone calls should be borne by the presiding officer, rather than the parties, and that all parties to the proceedings should be permitted to participate in the oral argument.

The Commission agrees with some of these comments and disagrees with others. Because of the difficulty in transcribing telephone calls in which several persons are participating, the Commission is not requiring that a court reporter transcribe arguments made in telephone conference calls or that minutes of the argument be prepared by the presiding officer and served on the parties. Instead the Commission has adopted a rule which provides that if the presiding officer requires oral responses, he or she shall issue a written order on the motion to compel. The order will summarize the views of the parties. This should create an adequate record for review. If a party disagrees with the presiding officer's summary of its views, it may file a motion with the presiding officer requesting that the order be modified so that it reflects accurately the views articulated by the party during the conference call. In adopting this approach the Commission is congnizant that it is not affording parties the right to submit written pleadings following oral argument. Such an approach would preclude a presiding officer from issuing an oral ruling during the conference call (which, though effective on issuance, would be followed by a written order as described above). However, if a presiding officer after hearing oral argument believes that written follow-up pleadings would be necessary to reach a sound decision on the motion, he or she may request such submissions.

The Commission also has not adopted the recommendation that the rule provide a standard minimum preparation time for the parties before oral argument. A party responding to a motion to compel covering one interrogatory would obviously need less time to prepare for argument than a party responding to a motion covering 25 interrogatories. Therefore, establishment of a minimum preparation time would deprive the boards of flexibility in establishing an appropriate schedule tailored to the circumstances. The Commission instead expects the presiding officer to set an appropriate schedule for oral argument on a case-by-case basis, taking into account the amount of work that will be required by the parties in preparing for oral argument.

The Commission agrees with the commenters that the presiding officer should bear the costs of the conference calls and that all interested parties should be permitted to participate in the call.

Finally, the Commission agrees that oral responses should not be used in the routine case. Oral responses should only be required where early completion of the proceeding is essential, such as in an operating license hearing where construction of the facility has been finished or may be finished prior to the completion of the hearing, in a hearing involving a request to expand spent fuel storage capacity where the plant is or may soon be operating without the benefit of a full core reserve storage capacity, or in a hearing on an operating license amendment involving a signficant hazards consideration where the issuance of the amendment is necessary for continued plant operation.

2. Use of Express Mail

Under the Commission's current rules, the presiding officer is not explicitly authorized to require service of documents by express mail (next day delivery). Accordingly, the rules provide five days for service. Use of express mail in limited circumstances would reduce the service time to two days.

The nuclear industry commenters generally supported adoption of the proposal. Intervenors in NRC proceedings opposed its adoption, emphasizing the cost of express mail. Intervenor commenters asserted that, if authorized, service by express mail should be required only when expedition is truly necessary.

Intervenor and industry commenters also pointed out that express mail service is not available in all cities, and therefore presiding officers could not require its use in some proceedings.

After reviewing the comments, the Commission has determined that on balance the arguments favoring adoption of the rule are more persuasive. The Commission emphasizes though that, because of the cost of express mail, it should only be required in those proceedings where early completion is essential. Parties should be required to use express mail to serve documents only on those parties (or the presiding officer) which are required to respond to the pleading. For example, a party may be required to serve interrogatories by express mail on the party who must answer the interrogatories. However, there is no reason to have that document served by express mail on the other parties or the presiding officer. When ordering use of express mail, the presiding officer should afford the parties the alternative of using first-class mail and filing the document three days earlier than would be required if express mail were used.

Finally, before ordering service by express mail the presiding officer should ascertain whether it is available. In cities where express mail is not available, the presiding officer obviously cannot order its use.

Regulatory Flexibility Act and Paperwork Reduction Act

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission hereby certifies that these rules will not have a significant economic impact on a substantial number of small entities. These rules affect the Commission's rules of practice and procedure by permitting expedition of the licensing process. The rules contain no recordkeeping or reporting requirements subject to the Paperwork Reduction Act.

Because the amendments are related only to matters of procedure, the Commission is making the amendments effective December 1, 1981.

Accordingly, pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter 1, Code of Federal Regulations, Part 2, are published as a document subject to codification to be effective December 1, 1981.

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47 FR 2286
Published 1/15/82
Effective 1/15/82

10 CFR Parts 2 and 50

Licensing Requirements for Pending Construction Permit and Manufacturing License Applications

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is adding to its power reactor safety regulations a set of licensing requirements applicable only to construction permit and manufacturing license applications pending at the effective date of this rule. The requirements stem from the Commission's ongoing effort to apply the lessons learned from the accident at Three Mile Island to power plant licensing. Each applicant covered by this rule must meet these requirements in order to obtain a permit or manufacturing license.

EFFECTIVE DATE: February 16, 1982.

FOR FURTHER INFORMATION CONTACT: Robert A. Purple, Deputy Director, Division of Licensing, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Telephone: (301) 492-7980.

SUPPLEMENTARY INFORMATION:

Background of the Rulemaking

The events leading up to the promulgation of this rule were discussed in detail in the Notice of Proposed Rulemaking, which appeared in the **Federal Register** on October 2, 1980, at pages 65247–65248. In that notice, the Commission reviewed some of the actions it had already taken in response to the accident at Three Mile Island and outlined the options it was considering with regard to the review of construction permit and manufacturing license applications. The Commission proposed to resume licensing using pre-TMI requirements augmented as necessary by new requirements identified in the Commission's TMI Action Plan, NUREG–0660. In connection with a request for public comments on these new requirements, the Commission noted that final rules might be issued on some or all of the matters discussed in that notice.

The Commission held a series of meetings regarding this proposed rule in January, February, and March of 1981. At its March 12 meeting the Commission decided that a further brief period of public comment was desirable prior to promulgation of a final rule to ensure that all interested persons have an opportunity to review the contents of the proposed rule and, in particular, have the opportunity to comment on the applicability of the proposed rule to the pending manufacturing license application. The additional comment period was discussed and noticed in the **Federal Register** on March 23, 1981, at pages 18045–18049.

The Commission particularly desired comment on whether or not the pending manufacturing license application, filed by Offshore Power Systems, Inc., should be covered by the proposed rule. At issue is whether the rule's requirements for the capacity of containments to withstand the effects of accident-generated hydrogen are sufficient when applied to floating nuclear power plants.

Analysis of Public Comments

The comments that were received and the Commission's responses are presented below in two parts. The first part addresses the comments received in response to the **Federal Register** Notice of October 2, 1980, regarding the proposed requirements set forth in draft NUREG–0718. The second part addresses comments responding to the March 23, 1981 notice containing the proposed requirements, as modified after consideration of comments, in the form of a proposed rule.

I. Comments to FR Notice of October 2, 1980. Comments were received from:

C. W. Rowley, Sand Springs, Oklahoma (Rowley)
Department of the Interior (USDI)
Marvin I. Lewis, Philadelphia, Pennsylvania (Lewis)
Bechtel Power Corporation, San Francisco, California (Bechtel)
Lowenstein, Newman, Reis, Axelrad & Toll (Lowenstein)
Offshore Power Systems (OPS)
Public Service Company of Oklahoma (PSO)
Boston Edison Company (BEC)
General Electric Company (GE)
Westinghouse Electric Corporation (*W*)
Portland General Electric Company (PGE)
Duke Power Company (Duke)
Combustion Engineering (CE)

The Commission's consideration of the comments received are reflected in part by revised text in the pertinent sections of NUREG–0718 and in part by the following discussion. The comments are grouped in five areas as indicated below and are referenced by the use of the abbreviations indicated above.

Comments on Proposed Requirements in NUREG–0718

The following is a discussion of comments received on specific NUREG–0660 items for which draft NUREG–0718 proposed requirements applicable to the pending applications.

I.B.1.1—*Organization and Management Long Term Improvements (PSO).*

II.J.3.1—*Management for Design and Construction (PSO).*

The commentor notes that there is an industry-wide effort related to these activities.

Discussion

The Commission is not entirely certain to what specific activity the commentor is referring. Liaison is maintained with the Institute for Nuclear Power Operations (INPO) which is in the process of conducting utility management audits using its own guidelines.

The classification of Action Plan Item I.B.1.1 has been changed to Category 2 (i.e., an item that is to be addressed at the operating license review stage rather than at the construction permit review stage) since it deals with operations management. The discussion that follows addresses the comments with respect to guidance availability.

Although the NRC is developing guidelines for utility organization and management for operations (I.B.1.1), and design and construction (II.J.3.1), the NRC is still required to make a finding on management and organizational capability prior to issuance of a construction permit or operating license, even if approved guidelines are not available. Therefore, as has always been the case, applicants are required to describe their organizational structure and management for design and construction, regardless of whether or not an industry approach is available or is being developed. For example, in the NRC reviews of utility management and organization for recently issued operating licenses, each one has been evaluated on a case-by-case basis. In conducting these reviews, the draft document "Guidelines for Utilities Management Structure and Technical Resources," NUREG–0731, which has been issued for public comment, was used.

The commentor also stated that NRC has ignored design and construction management guidance in response to Action Plan II.J.3.1. This is not the case. Draft guidelines for this task were prepared and have been circulated for internal comment. The guidance will be included in the final version of NUREG–0731 or in a separate document.

I.C.9—*Long-Term Program Plan for Upgrading of Procedures (PSO).*

A commentor noted that it would be difficult to describe in any significant detail, until after January 1982, the extent to which that commentor's program will be coordinated with INPO activities.

Discussion

In consideration of the comment the Commission has modified this requirement, which called for applicants to describe how their program would be coordinated with INPO activities. The modification requires that applicants ensure coordination, to the extent possible, of their program with INPO and other industry efforts.

I.D.2—*Plant Safety Parameter Display Console (Bechtel).*

The commentor suggested adding a reference to the document where the pertinent staff criteria can be found.

Discussion

Reference to NUREG–0696 has been incorporated in NUREG–0718 as suggested.

I.D.4—*Control Room Design Standard* (Bechtel, BEC).

The commentor noted that the IEEE standard reference in the requirement is not yet available.

Discussion

The Commission has reconsidered this proposed requirement and has placed this Action Item in Category 1 (i.e., an item that is not applicable to the construction permit review). However, the need was found to strengthen the I.D.1 requirement governing control room design revisions. I.D.1 places general requirements on the ML and CP applicants.

I.E.4—*Coordination of Licensee, Industry and Regulatory Programs* (PSO). The commentor objected to describing, prior to issuance of a CP, efforts to evaluate and factor in applicable experience at similar plants on the gounds that the Nuclear Safety Analysis Center (NSAC) is developing a generic industry plan and that a separate response by the utility could undermine the generic industry program.

Discussion

The Commission considers it important that those responsible for the design and construction of nuclear plants have a program in place prior to issuance of a CP or ML (even if that program is later superseded by an industry program) that assures an early awareness of safety problem areas and areas of safety improvements that arise elsewhere. The Commission would have no objection if a utility were to improve such a plan at a later date by adopting a plan worked out generically between the industry and the NRC staff. The requirements of I.E.4 are covered by I.C.5.

II.A.2—*Site Evaluation of Existing Facilities* (USDI, Lewis, Bechtel, Lowenstein, PSO, BEC, CE).

Siting was one of the four areas that the Commission identified in the October 2, 1980 notice of proposed rulemaking as deserving special attention. Several comments (Bechtel, Lowenstein, PSO and BEC) cited Section 108(b) of Pub. L. 96–295 (NRC FY 80 Authorization) and express or imply concern that the proposed requirements under II.A.2 are not consistent with exemption from future regulations that are to be promulgated under Section 108.

Discussion

The Commission believes that the proposed requirements would not have been inconsistent with Section 108. However, based on preliminary staff evaluation of the sites involved, as well as the requirement added in II.B.8 for each CP applicant to perform a plant/site specific probabilistic risk analysis, the Commission has reclassified II.A.2 to Category 1.

The USDI and Lewis comments are addressed elsewhere in this document under the discussion of comments on the methods of implementing the requirements.

II.B.1—*Reactor Coolant System Vents (Bechtel).*

The commentor suggested that this item be removed since II.B.8 requires applicants to describe the degree of design conformance with the proposed interim requirements.

Discussion

Since the proposed interim rule, related to hydrogen control and degraded core considerations, as published in the **Federal Register** (45 FR 65466, October 2, 1980), did not include a requirement to demonstrate by analysis that direct venting will not result in violations of combustible gas concentration limits, II.B.1 has been revised to eliminate the requirement.

II.B.8—*Rulemaking Proceeding on Degraded Core Accidents (Bechtel; BEC; Lewis; Lowenstein; OPS; PSO; W; CE).*

Most comments received opposed requiring any concrete actions in the area of accommodating degraded-core accidents on the part of the applicants prior to completion of the rulemaking process. Several commentors noted that the requirement in this area, as expressed in the draft NUREG–0718, was too openended and did not clearly set forth acceptance criteria.

Discussion

Degraded core rulemaking was another of the four areas the Commission identified in the October 2, 1980, Federal Register notice as deserving special attention. As the rule was drafted in that notice, the applicants would have been required to describe the extent to which their designs conform to the proposed interim hydrogen control rule and to provide reasonable assurance that issuance of a CP or ML would not foreclose the ability to accommodate potential requirements resulting from the rulemaking proceedings. The Commission also listed some features as potential requirements and proposed that the applicants submit an evaluation of the preventive and mitigative features having a potential for significant risk reductions that they would propose to include at their facilities.

In view of the comments and upon further consideration, the Commission has revised this requirement. The principal objective in the revision has been to take advantage of the fact that, for a plant that has not yet begun construction, it should be relatively easier to avoid foreclosing design modifications resulting from the rulemaking. For some of the potential design requirements that might be required by the final rule, it is relatively easy to ensure that they can be accommodated at any stage of construction (e.g., by providing large containment penetrations to accommodate a filtered vented containment concept). However, to extend this approach to every conceivable rule requirement could easily lead to major redesigns of these plants, for which considerable design has been completed, possibly causing unnecessary delays in their construction. On the other hand, to do nothing at this time would very likely result in foreclosure of the practical implementation of some of the future requirements.

Taking into account the fact that the plants represented by the pending applications are of the most recent design and that the proposed sites are comparatively good sites, the Commission has adopted a policy of allowing construction to proceed while minimizing foreclosure of plant modifications in the structural design area that may result from the rulemaking proceeding on degraded core accidents. Specifically, as reflected in II.B.8, prior to issuance of a CP or ML, the applicants would be required to commit to (1) performing a site/plant probabilistic risk assessment (This risk study would encompass many of the other concerns related to siting, systems reliability, and degraded core accidents), (2) making provisions for one or more containment penetrations for possibly venting the containment, (3) providing hydrogen control measures, and (4) providing preliminary design information sufficient to demonstrate, given a 100 percent fuel clad metal-water reaction accompanied by either hydrogen burning or post-accident inerting, that (a) containment integrity will be maintained at an internal pressure of at least 45 psig, (b) systems necessary to insure containment integrity will perform their intended function, (c) facility design will provide reasonable assurance that uniformly distributed hydrogen concentrations cannot exceed 10 percent (controlled burning) or, in the alternative, the post-accident atmosphere will not support hydrogen combustion, (d) facility design will provide reasonable assurance that hydrogen will not collect in areas where localized concentrations could unintentionally burn or detonate and result in loss of containment integrity or loss of appropriate mitigating features, and (e) inadvertent operation (based on CO_2) post-accident inerting hydrogen control system can be safely accommodated during plant operation.

II.C.4—*Reliability Engineering* (Bechtel; Lowenstein; PSO; W; Duke).

Reliability engineering was one of the four areas that the Commission identified in the October 2, 1980 notice of proposed rule making as deserving special attention.

The commentors generally expressed the view that reliability engineering is an important tool in designing for safety, but felt that, because the methodology is not well developed, it would be inappropriate to require extensive analysis as a prerequisite for a construction permit. Most commentors believed that a commitment to incorporate reliability engineering during final design, after CP issuance, would be appropriate. However, one commentor argued that no requirement in this area should be specified until the degraded core rulemaking is completed.

Discussion

The requirement under II.B.8 in the revised NUREG–0718 to perform an overall plant/site risk study will, in effect, encompass and go beyond the simplified reliability analyses called for in the draft NUREG–0718. The comprehensive risk study is expected to achieve a more thorough evaluation of plant safety and will provide a sounder technical basis for making decisions regarding potential plant improvements. Accordingly, the more limited effort called for in the draft NUREG–0718 has been replaced by the risk study requirement of II.B.8.

II.D.2—*Research on Relief and Safety Valve Test Requirements* (Bechtel, BEC).

The commentor noted that the two entries shown for this item should either be combined or one entry deleted.

Discussion

Action Item II.D.2 has been placed in Category 1 since it deals with research on generic tests. Action Item II.D.1 has been expanded to include the information presently shown in II.D.2.

II.F.3—*Instrumentation for Monitoring Accident Conditions* (Regulatory Guide 1.97) (PSO).

The commentor expressed concern that since Regulatory Guide 1.97 has not been issued, it will be difficult for the utilities to meet the NUREG–0718 requirements in a timely manner.

Discussion

Revision 2 to Regulatory Guide 1.97 was issued on December 24, 1980.

III.A.1—*Improve Licensee Emergency Preparedness—Short Term (BEC, PSO).*

III.A.2—*Improve Licensee Emergency Preparedness—Long Term (BEC, PSO).*

The commentors suggested that the requirements in these two items be combined and noted that the requirements should only represent information submitted at the CP review stage.

Discussion

Item III.A.1.1 in the TMI Action Plan was intended to apply only to operating reactors and certain operating license applicants, not to CP and ML applicants. For CP and ML applicants, the long term item III.A.2 called for licensees to participate in the development of guidance and criteria, which has now been completed. The Commission has issued new regulations to upgrade emergency preparedness planning for NRC–licensed facilities. These new regulations were issued on August 19, 1980, and became effective on November 3, 1980. Since item III.A.2 is now covered by the regulations, it has been removed from NUREG–0718.

Item III.A.1.2 has been revised to provide clearer guidance by specific reference to NUREG–0696.

Special Consideration Areas of Siting, Degraded Core Rulemaking, Reliability Engineering, and Emergency Preparedness

(See the discussion above under II.A.2, II.B.8, II.C.4, and III.A.1–.2)

Deviations From the Standard Review Plan

Several of the responses commented on the proposed requirements to document deviations from the Standard Review Plan. On October 9, 1980, another Notice of Proposed Rulemaking

was published in the Federal Register (45 FR 67099) which also detailed requirements for documenting deviations from the SRP. This second notice not only reiterated the documentation requirements of the first notice, but also extended the requirements to operating plants and construction permit holders. A comprehensive final rule which will also include action for the pending CP and ML applications is under consideration in connection with 45 FR 67009. Accordingly, no special requirement on this subject will be included in this rule.

Comments on Instruction to Atomic Safety and Licensing and Appeal Boards (Lowenstein; PSO; BEC)

The notice of proposed rulemaking also requested comments on the extent to which judgments reached by the Commission on siting, emergency preparedness, reliability engineering, degraded core rulemaking, and the requirements of NUREG–0718 should form the basis for instructions to licensing and appeal boards in the CP and ML proceedings.

One commentor (Lowenstein) suggested that the licensing boards should be instructed that strict time schedules are to be imposed and enforced for completion of litigation. The Commission anticipates that licensing boards would, under present authority, impose and enforce appropriate schedules.

With respect to siting, this commentor recommends that the licensing boards be permitted to entertain contentions that any part of additional requirements proposed by the NRC staff as a result of the proposed rule on siting are unnecessary or that such proposed requirements are not being complied with, but that requirements beyond those proposed by the staff may not be entertained and that boards' authority to raise issues *sua-sponte* should be subject to the same limitations. Also, this commentor would have the boards instructed not to entertain contentions that alternate sites be considered due to demographic considerations in view of the provisions of Section 108(b) of the NRC appropriation authorization for Fiscal Year 1980, discussed under item II.A.2 above.

With respect to degraded core rulemaking, the above commentor would have the licensing boards instructed to limit the litigation in a fashion similar to that proposed by this commentor on the siting issue, namely by restricting contentions to the NUREG–0718 requirements applicable to the CP review stage, including the requirement to consider certain preventive and mitigative features.

With respect to reliability engineering, the above commentor would have the licensing boards instructed that they may only entertain contentions on the nature, method of conduct, and completion dates of the studies and the program to assure that the results are reflected in the final design. Here also, this commentor recommends that the authority of licensing boards to raise issues *sua-sponte* be subject to these same limitations.

Another commentor (PSO) believes that the Commission should issue a rule directing licensing boards to resume licensing proceedings in accordance with Option 1 (which the commentor believes would entail further notice and opportunity to comment before implementation). (The options are described in the following section.) If, however, Option 3 is adopted by the Commission, then this commentor would propose that the rule should be issued and made effective within 30 days after publication in the **Federal Register.**

The third commentor (BEC), who also favors Option 1, would have the licensing boards instructed that they may entertain contentions that one or more NUREG–0718 requirements applicable to the CP review stage are not complied with but may not entertain contentions that requirements beyond these are necessary. This commentor would also have the licensing boards' authority to raise issues *sua-sponte* subject to these same limitations.

Discussion

The Commission has decided that Option 3 should be embodied as a rule, to be effective 30 days after publication of the notice in the **Federal Register.** This rule, like other Commission regulations, may be challenged in accordance with 10 CFR 2.758.

Comments on the Method of Implementing the Requirements

In the notice of proposed rulemaking, three options for resuming licensing on the pending CP/ML applications were presented. Briefly, they were as follows:

Option 1

Resume licensing using the pre-TMI requirements augmented by the applicable requirements identified in the Commission's June 16, 1980 Statement of Policy regarding operating licenses.

Option 2

Take no further licensing action until the rulemaking actions described in the Action Plan, NUREG–0660, have been completed.

Option 3

Resume licensing as indicated under Option 1 above, but also require certain additional measures or commitments in selected areas (e.g., those that will be the subject of rulemaking.)

A majority of those commenting favor Option 1 which, with respect to the TMI Action Plan, would, in effect, treat the pending applications as if they were the last of the present generation of nuclear power plants. The applicants for these plants would not, under this option, be required to address the four special areas cited in the notice. Reasons cited for selecting that option include:

Option 3 could significantly delay CP licensing process (Bechtel, PGE)
Option 3 constitutes excessive and unnecesary regulation (Lowenstein)
pending CP applicants should be treated like present CP holders (PSO)
"additional measures" of Option 3 would be inordinately costly (BSE)
Option 3 proposes a different and escalated set of TMI-related requirements (GE)
Option 3 adds uncertainty to the review process by requiring commitments to future events (CE)
Sufficient "in the interim" and can be implemented in a realistic and cost effective manner (*W*)
Reduce dependence on foreign oil (Rowley)

One commentor (OPS) suggested that either Option 1 or Option 3 would provide a reasonable basis for resuming licensing.

One commentor (Duke) proposed its affected units (Perkins) be exempted from the rulemaking altogether because those units are intended to be identical to other units (Cherokee) already granted CP's.

One commentor (USDI) recommended that no construction permits be issued until the siting rulemaking has been completed. While it is true that a siting rule is being formulated, it is not expected to be so drastically different from the present guidelines as to make these previously evaluated sites grossly deficient. The Commission therefore declines as a matter of policy to delay consideration of the pending applications for conclusion of the siting rulemaking.

One commentor (Lewis) asserted that any action at this time is unnecessary and/or premature. Among other things the commentor stated that there is no demand or "need for power" from new plants at this time. The Commission finds that those considerations are outside the scope of this rulemaking. Need for power and related issues have been or will be addressed in the individual CP or ML proceedings by the licensing boards. This commentor also stated that many new requirements will eventually be developed in answer to the accident at TMI-2. Included are proposed rule changes on population density, and consideration of "Class 9" accidents. In his view, concurrent consideration of several rulemakings at one time makes for duplicative efforts. However, the comments in this regard overlook the fact that ongoing licensing proceedings are always subject to matters in rulemaking and that applications are in any event judged against current licensing requirements.

On balance, the Commission continues to believe that Option 3, as modified by revisions to II.A.2, II.B.8, and II.C.4, is the most suitable course of action to take.

II. Comments to FR Notice of March 23, 1981. Comments were received from:

1. J. D. Sloan, Charlotte, North Carolina (Sloan)
2. Southern Company Services, Inc., Birmingham, Alabama (SCS)
3. Minnesota Pollution Control Agency, Roseville, Minnesota (MPCA)
4. Offshore Power Systems (OPS)
5. Baltimore Gas and Electric Company (BG&E)
6. Boston Edison Company (Boston Edison)
7. Gilbert Associates, Inc., Reading, Pennsylvania (Gilbert)
8. Town of Hampton Falls, New Hampshire (Hampton Falls)
9. Marty Casella, Sun Valley, California (Casella)
10. Jane J. Estes, Blacksburg, Virginia (Estes)
11. Stone & Webster Engineering Corporation, Boston, Massachusetts (S&W)
12. Atomic Industrial Forum, Washington, D.C. (AIF)
13. Edison Electric Institute, Washington, D.C. (EEI)
14. Virginia Electric and Power Company (VEPCO)
15. Combustion Engineering, Inc., Windsor, Connecticut (CE)
16. Marvin I. Lewis, Philadelphia, Pennsylvania (Lewis)
17. Robert Alexander, Houston, Texas (Alexander)
18. Committee on Nuclear Quality Assurance, American Society of Mechanical Engineers (NQA)
19. Bechtel Power Corporation, San Francisco, California (Bechtel)
20. Consolidated Edison Company of New York (Con Ed)
21. General Electric Company, San Jose, California (GE)
22. Carolina Power & Light Company (CP&L)
24. Florida Power Corporation (FPC)
25. Lowenstein, Newman, Reis & Alexrad (Lowenstein) on behalf of Houston Light & Power Company and Puget Sound Power and Light Company
26. Commonwealth of Massachusetts (Massachusetts)
27. Tampa Electric Company (TEC)
28. Business and Professional People for the Public Interest, Chicago, Illinois (BPI)
30. Westinghouse Electric Corporation, Pittsburgh, Pennsylvania (W)
31. Public Service Company of Oklahoma (PSO)
33. Portland General Electric Company (PGE)
34. Commonwealth Edison Company (CEC)
35. Middle South Services, Inc., New Orleans, Louisiana (MSS)
36. Florida Power & Light Company (FP&L)
37. Central Power and Light Company (Central P&L)
39. Tennessee Valley Authority (TVA)
40. Ebasco Services, Inc., New York, N.Y. (Ebasco)
42. Babcock & Wilcox, Lynchburg, VA (B&W)
43. D. Marrack, Bellaire, Texas (Marrack)

(Letters numbered 23, 29, 32, 38 and 41 are not listed because they are duplicates of the letters numbered 6, 24, 21, 32 and 11, respectively. The letters numbered 1, 8, 9, 10 and 26 contain no comments on the proposed rule).

The staff's consideration of the pertinent comments received is provided in the following discussion. The comments are grouped as indicated below, with the source of the comments referenced by use of the abbreviations indicated above.

1. Inclusion of the ML Application

The following is a discussion of the comments received on including the application for a Manufacturing License (ML) in the rule for licensing requirements for pending applications for Construction Permits and Manufacturing Licenses.

One commentor (Lewis) clearly favors outright exclusion of the ML from the rule. The basis for exclusion presented by the commentor is that Offshore Power Systems lacks a customer for the Floating Nuclear Plant (FNP).

A majority (16) of the (20) commenting letters that address the issue strongly favor including the ML in the rule. Three others (Boston Edison, EEI, Lowenstein) believe the ML should be included, but not if this results in a delay in promulgation of the rule for the CP applications. Some of the reasons given for this support are the standardized plant concept (BG&E, OPS, VEPCO, CON ED, CP&L, FPC), conservation of resources, "diversity of fuel supplies", and "innovation" (BG&E). Also, the considerable expenditure of dollars, expert engineering man-years, and support facility construction are noted.

OPS, particularly, states that exclusion of the ML from the rule would "* * * greatly damage the concept of standardization and would cast substantial doubt on whether the incentives perceived to result from standardization in fact exist." OPS further submits that the investment in the FNP was made "* * * in reliance on our understanding that the standards to be applied to the Manufacturing License are the same as those which apply to Construction Permits, with only such distinctions as are set out in 10 CFR Part 50, Appendix M" and that to segregate them now would "* * * insert * * * a commercial requirement completely at odds with the Manufacturing License concept and the Commission's prior licensing philosophy." OPS asserts that the requirements in Subsection (3)(v) of the proposed rule are "* * * entirely appropriate for application to Floating Nuclear Plants", and that "[D]esign features required by the rule can and will be incorporated into the Floating Nuclear Plant design * * *". OPS also notes that "[M]any of the Near-Term Construction Permit plants utilize containments with volumes and design pressures comparable to the ice condenser containment employed in the Floating Nuclear Plant", and that "* * * information reported at March 1, 1981 ACRS meetings * * * indicate (sic) that the capability to increase containment strength is very nearly the same for the Near-Term Construction Permit plants and the Floating Nuclear Plant * * *."

Discussion for Inclusion of the Manufacturing License in the Rule

The Commission generally agrees with the comments that favor inclusion of the ML application in the rule and has, therefore, included it.

2. Comment Period Too Short

One commentor (Gilbert) stated that, "Based upon the numerous criteria contained in this proposal, and the potential monumental impact of those requirements, the 20-day comment period is too short and restrictive for public rulemaking in spite of the NRC's rationalization of this time interval."

Discussion

The 20-day comment period provided in the notice printed in the **Federal Register** on March 23, 1981 (46 FR 18045) was considered by the Commission to be sufficient, considering the 45-day comment period provided in a previous notice on October 2, 1980 (45 FR 65247). Promulgation of the rule will provide the affected parties with a firm basis for responding to TMI-related requirements, thereby eliminating the present uncertainty and its attendant potential for unnecessary delay.

3. Application of the Proposed Rule to Present CPs and OL Applications

One commentor (BPI) submits that "the new rule, if enacted, should be made applicable to present holders of construction permits, as well as to applicants for construction permits and manufacturing licenses. To decline to so apply the amendment, especially to plants which are in the very early stages of construction, suggests that the Commission is not seriously attempting to implement the needed upgrading of safety for all nuclear plants." Another commentor (Marrack) argues that all plants not yet operating should meet the minimum improved standards.

Discussion

Holders of construction permits have already been informed by letter that they must meet the TMI-related requirements contained in NUREG–0737. There is an ongoing rulemaking to codify these requirements in the Commission's regulations. This action will ensure that the bulk of the requirements that are contained in this new rule for pending CP/ML applicants will be made applicable to all holders of construction permits. For those areas in this new rule that go beyond the requirements of NUREG–0737 (such as those related to containment strengthening and other hydrogen control measures), the Commission, in the near future, intends to consider their applicability to present CP holders on a case-by-case basis.

4. Imposition of New Requirements

One commentor (FPC) urges "the Commission to impose new licensing requirements on plants during the licensing process only after a cost/benefit evaluation has been completed utilizing identified safety benefit compared to financial requirements to implement i.e. containment strength. We have a concern that without such evaluations licensing requirements may be imposed with minimal increase or perhaps no increase in overall safety at significant costs. This will quickly erase the nuclear alternative as viable and severely limit our energy resources." Another commentor (CE) also recommends that any major modifications should undergo complete cost/benefit assessment. In addition, the commentor urges "that this requirement should be coordinated with other rulemaking proceedings in progess, specifically the development of an overall safety goal."

Another commentor (Lowenstein) said, "we also think it essential that the Commission recognize that in many instances applicants have already completed designs, procured equipment, or committed to fabrication of equipment on much of the proposed plants. The Commission should make clear to the NRC staff that the new requirements should be interpreted to minimize extensive redesign and procurement of new equipment to replace that already purchased."

Discussion

The Commission agrees that new requirements should be based on favorable cost/benefit evaluations, but this is not possible, in quantifiable terms, at present due to the lack of a specified safety goal. The Commission and its staff recognize that unnecessary extensive redesign and procurement of new equipment should be avoided. However, in its extensive deliberations concerning TMI-related requirements, the Commission has decided that the requirements in the new rule are necessary for protection of the public and that their costs are not exorbitant. Acceptable alternative methods of meeting the requirements stated in the rule will be considered.

5. Imposing Requirements Now Under Rulemaking

Several commentors (S&W, CEC, Lewis, Ebasco) oppose the imposition of requirements subject to other rulemaking proceedings, particulaly relative to degraded core conditions, as premature.

Another commenter (*W*) said that "in light of the ongoing generic NRC proceedings with respect to safety goals and methodology, degraded core cooling, siting and emergency planning, the Commission should make it clear that the final rule when adopted is an interim rule to be applied pending the outcome of these proceedings and the risk assessments required by the rule." "Paragraphs (e)(1)(xv), (e)(3)(iii), (e)(3)(iv), (B thru D): Each of these items are either premature impositions of requirements not yet authorized by the NRC or are clearly the subject of current ongoing rulemaking e.g. hydrogen control and degraded core rulemaking. To impose these requirements at the CP stage precludes the full airing of these issues prior to assumption by the applicant of construction costs," stated one commentor (CEC).

Discussion

This rule does include some requirements which are subjects of other ongoing rule-making proceedings. The purpose of including these requirements in this rule is to ensure that future requirements are not rendered impractical because construction has been allowed to proceed on these plants without having made provisions for them.

6. NUREG–0718 Is Premature, Limited and Misleading

One commentor (Lewis) states that "the staff guidance in NUREG–0718 * * * is so limited and so misleading that it will probably be a matter of civil suit between NRC and Licensee's. Many licensee's will be able to argue that the staff guidance mislead them into believing that new requirements would be easy-to-meet and low cost." The commentor therefore, suggested that NUREG–0718 be eliminated.

Discussion

The Commission is not aware of specific additional guidance the commentor would have it provide at this time. The staff will provide applicants with additional guidance as the need arises. Eliminating NUREG–0718 at this time would remove all guidance and could lead to more instability in the review process.

7. Objections to Detail of the CP/ML Rule

Two commentors (Gilbert, CEC) object to the regimentation, "great detail", and "specificity" of placing such a rule in the Code of Federal Regulations. They support the use of Regulatory Guides, Standard Review Plans, and/or various NUREG documents. One commentor (Gilbert) goes on to state: "The current proposal applies to but seven pending applications, yet proposes to more than double the volume of 10 CFR 50.34. Furthermore, a number of the individual requirements are so design specific as to preclude the possibility of alternate designs or solutions in the future. We thus see these new proposed regulations as in conflict with both President Reagan's directive for both simplified regulatory requirements, as well as his stated beliefs that new nuclear plants should not be unduly regulated into oblivion * * * We believe that the general goals and objectives of proposing the new 10 CFR 50.34(e) can be obtained through means other than the new regulations (as has been done on plants undergoing OL review) on a case-by-case or even a generic basis, and that imposing these requirements by use of a new 10 CFR 50.34(e) is unwarranted and without justification."

Discussion

The regulatory authority provided by a rule ensures a clear and concrete way to impose the necessary requirements in the wake of lessons learned from the TMI–2 accident. Separate rules for the CP/ML applicants and the OL applicants will clarify the specific requirements the Commission considers necessary for plants at these stages in the licensing process. Excessive details have been removed from the proposed rule; where details are specified, the Commission has decided they are necessary to ensure the safety of the public.

8. Comments on the Method of Implementing the Requirements

One commentor (PSO) provided comments objecting to Option 3* on the basis of timing, "i.e., this option requires the completion of a myriad of time consuming engineering activities and analyses before issuance of construction permits. On the other hand, Option 1 would have required only that an applicant make necessary commitments, including reasonable implementation schedules, before issuance of the construction permits."

Another commentor (TVA) expressed the belief that the major issues in the proposed rule have not been resolved sufficiently to process final rule changes at this time. TVA suggested the following approach as a more effective means of accomplishing the changes in licensing requirements:

1. Require that all pending construction permit and manufacturing license applicants commit to implement the final rules that grow out of the money pending post-TMI rulemakings, such as probabilistic risk assessment methodology, safety goal, siting, degraded core, etc.
2. Implement only those changes in the proposed rule which have been promulgated and issued for use by the near term operating license plants. For other changes, retain the existing rules pending completion of the post-TMI rulemakings.

Discussion

The Commission has adopted Option 3, which will ensure that approved action items in the TMI Action Plan are applied to the new CPs and ML and will provide for early consideration of these added safety measures so as to minimize the costs of incorporating them into the design of the facility.

9. Comments on Prompt Adoption of the Rule

Many of the commentors (AIF, EEI, Lowenstein, etc.) expressed strong support for the prompt adoption of the rule. One commentor (Boston Edison) submitted "that the Commission would be shirking its vital responsibility in this area if it did not issue a rule such as this and if this rule were not intended as binding upon the Commission's subsidiary boards." Another stated, "C-E agrees with the Commission's intent of defining the set of TMI-related requirements that are both necessary and sufficient to resume NRC review and approval of pending and ML applications. These requirements (as modified to reflect public comments) should therefore be issued expeditiously in conjunction with a clear enunciation of the sufficiency of those requirements, so that NRC staff action on pending applications can recommence."

Discussion

The Commission believes that issuance of the final rule is the proper response to these comments.

10. Basis for Compliance With the Rule

A. One commentor (Bechtel) noted that most of the items contained in the proposed rule reference action plan items in NUREG–0718 and NUREG–0660 and recommended that where the referenced paragraph in these NUREGs amplifies the requirements of the rule, it should be recognized that as an acceptable means of compliance. Another commentor (Ebasco) also pointed out that the proposed rule imposes new requirements in areas where final NRC acceptance criteria have not been finalized and that NRC policy relative to implementation of those criteria must be flexible because of the different types of requirements. To expedite the CP hearing process, Ebasco suggested that "compliance with NUREG–0718 be considered prima facie evidence that TMI requirements have been met."

Discussion

The Commission agrees with the comments. The Commission has reviewed NUREG–0718 and has concluded that the position contained therein can provide a basis for responding to the TMI–2 accident. Applicants may, of course, propose to satisfy the rule's requirements by a method other than detailed in NUREG–0718, but in such cases must provide a basis for determining that the requirements of the rule have been met. NRC acceptance criteria will be sufficiently flexible to permit appropriate alternative methods of meeting the requirements.

B. Two commentors (Boston Edison, Lowenstein) noted that "Some of the provisions of the proposed rule required the applicant to conduct studies and submit them to the NRC for review and appropriate action. Boston Edison pointed out that "these studies will be completed after issuance of the construction permit, in some instances several years later. We believe it is necessary to make clear that the construction permit licensing boards or appeal boards do not retain jurisdiction or supervisory authority over the applicant and NRC staff for the purpose of reviewing the completed studies. This would extend the construction permit proceeding far beyond the actual issuance of the permit and continue needless uncertainty. Issues concerning the required studies are appropriate matters for the operating license stage review." Another commentor (Ebasco) noted that NRC will have received the studies, in some instances, prior to SER issuance for CPs since some of these study requirements were applicable to operating plants and are generic in nature. Ebasco suggested that the studies be excluded from the (CP) hearings.

Discussion

The Commission does not expect its adjudicatory boards to retain jurisdiction or supervisory authority over fulfillment of those requirements for studies to be completed subsequent to issuance of the CP. However, the Commission does expect the staff to review such studies in a timely manner and to take appropriate action. Regarding the Ebasco comment, one of the study requirements has been deleted for the reason suggested.

C. Another commentor (Lowenstein) stated, "It is essential that the Commission make clear that this regulation, along with the existing regulations, establishes an adequate and sufficient response to the Commission's post-TMI requirements. While the notice intimates this on page 18046 (of the FR notice), we urge that it be explicitly stated in the rule."

Discussion

In the Notice of Rulemaking (46 FR 18045) published on March 23, 1981, under Substance of the Rule, the Commission stated, "It is the Commission's view that this new rule, together with the existing regulations, form a set of regulations, conformance with which meets the requirements of the Commission for issuance of a construction permit or manufacturing license." The Commission reaffirms this view with the exception of hydrogen control measures for the manufacturing license, and, to eliminate any ambiguity regarding its intent, is amending its special review procedures in 10 CFR 2.764 to delete the statement in paragraph (e) that compliance with existing regulations may turn out to no longer warrant approval of a license application. However, it should be noted that the Commission also indicated in that notice that some elements in the TMI Action Plan have not been acted upon and thus may be required on the basis of future rulemaking.

11. Additional TMI-Related Requirements

One commentor (MPCA) suggested that additional items of the TMI Action Plan should be incorporated into the rule as CP/ML licensing requirements. The specific items in NUREG–0718 and NUREG–0660 suggested for inclusion in the rule are:

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*Option 3 requires certain measures or commitments in selected areas (e.g., those that will be the subject of rulemaking) in addition to those imposed by Option 1. Option 1 is to resume licensing using the pre-TMI requirements augmented by the applicable requirements identified in the Commission's June 16, 1980 Statement of Policy (now replaced by the December 18, 1980 Statement of Policy) regarding operating licenses.

1.A.4.1 Initial Simulator Improvement
I.C.1 Short Term Accident Analyses and Procedures Revision
II.B.4 Training for Mitigating Core Damage
II.B.6 Risk Reduction for Operating Reactors at Sites with High Population Densities
II.B.7 Analysis of Hydrogen Control
II.E.2.1 Reliance on ECCS
II.E.2.3 Uncertainties in Performance Predictions
II.E.3.2 Systems Reliability
II.E.3.3 Coordinated Study of Shutdown Heat Removal
II.J.1.1 Establish a Priority System for Conducting Vendor Inspections
III.D.1.2 Radioactive Gas Management
III.D.1.3 Ventilation System and Radionuclide Adsorber Criteria
III.D.1.4 Radwaste System Design Features to Aid in Accident Recovery and Decontamination
III.D.2.1 Radiological Monitoring of Effluents
III.D.2.3 Liquid Pathway Radiological Control
III.D.2.4 Offsite Dose Measurements

Discussion

The Commission has considered incorporating each of these requirements into the proposed rule, but for the reasons stated below it has determined that none of these should be added.

Items II.E.2.3, III.D.1.2–4, III.D.2.1 and III.D.2.3–4 have been judged lower priority TMI issues as reflected by task initiation dates of FY82 or later. Because of their relative low priority, the Commission believes their incorporation into the CP/ML rule is unnecessary. However, the results and conclusions of these tasks will be appropriately considered during the OL review.

A second group of suggested items is covered in other TMI action tasks that are included as requirements in the proposed rule. Items II.B.6 and II.E.3.2,3 are intended to be included in § 50.34(f)(1)(i), the required plant/site specific probabilistic risk assessment. Item II.B.7 is covered by § 50.34(f)(2)(ix) and (3)(v). Items I.A.4.1 and I.C.1. are applied to operating plants and the substance is included in § 50.34(f)(2) (i) and (ii), respectively, for these CP/ML applications.

Another group of items is not applicable for various reasons. Item II.J.1.1 applies to NRC and not to CP/ML applicants. Item II.B.4, pertaining to crew training, is more appropriate as an OL item. Finally, II.E.2.1 requires the assessment of ECCS data by operating plant licensees and is not applicable to CP/ML applicants.

In summary, the Commission has reviewed and considered all of the additional requirements suggested by MPCA and has determined that they are either covered by provisions of the proposed rule or are not applicable or appropriate for construction permit and manufacturing license applications.

12. Comments on Certain Rule Requirements

The following discussion responds to the comments received on the specific items of 10 CFR 50.34(f) listed below:

(1)(i)—Plant/Site Specific PRA Study

A. Two commentors (S&W, CEC) point out that the NRC has not yet defined the methodology to be used in the PRA study.

Discussion

The Commission notes that a PRA Procedures Guide was issued as a draft for discussion by an IEEE technical symposium in October 1981, and will be issued in proposed final form for consideration at an ANS conference in April 1982. It is expected that the Guide will be published soon after the ANS conference. Meanwhile, plans for a PRA study, and the actual conduct of the study, need not wait until the safety goal and degraded core cooling rulemakings are resolved. During a meeting with the CP/ML applicants on April 8, 1981, the NRC staff made available a PRA program outline which should serve as a guideline for CP/ML applications. The program outline addresses issues such as the scope of the PRA study, how the PRA study should be performed, what should be considered in setting up a schedule, and, most importantly, how the results of the risk study should be factored into the design, fabrication and eventual operation of the plant to improve the reliability of core and containment heat removal systems. It is reasonable to expect that an applicant can utilize the staff guidelines to develop its own program for performing a meaningful PRA study. Consequently, the Commission will retain this requirement.

B. Another commentor (GE) expressed the belief that "completion of the PRA studies and comparison to a reasonable safety goal will demonstrate that the Boiling Water Reactor includes design features which ensures that the public health and safety is protected. If, on the other hand, the results of the studies * * * show that further risk reduction is appropriate, plant modifications * * * should be considered".

Discussion

Based on the risk studies performed to date, accident sequences relating to core and containment heat removal systems contribute substantially to overall accident risk. To reduce such risk, alternate system designs for core and containment heat removal systems should be considered and PRA studies should be performed in comparison with the PRA study for the original design. The outcome of the comparison should be selection of a system design from among several design alternatives that incorporates significant improvements in the reliability of core and containment heat removal systems.

C. Two commentors (TVA, B&W) suggested that the improvements that may result from the risk assessment should be those that are significant with respect to public health and safety, not just generally significant and practical.

Discussion

The aim of the probabilistic risk assessment, as expressed in the requirement, is to seek such improvements in the reliability of core and containment heat removal systems as are practical and do not impact excessively on the plant. The Commission believes that such improvements in reliability would also be significant with respect to public health and safety. Accordingly, the Commission does not consider it necessary to change the language of the requirement.

(1)(ii)—Auxiliary Feedwater System Evaluation

Two commentors (CEC, TVA) argued that the existence of paragraph (1)(i) regarding performance of a probabilistic risk assessment (PRA) makes paragraph (1)(ii) superfluous, since a PRA study would include the analyses and reviews discussed in (1)(ii) and in paragraphs (1)(iii)–(xii).

Discussion

The Commission does not agree with this comment. It is not at all certain that the PRA would necessarily include all parts of the evaluation called for in paragraph (1)(ii). The result might be non-uniform and incomplete submittals by the applicants, with consequent time-consuming reiterations. It is, therefore, important that the three parts of the auxiliary feedwater system evaluation be specified. However, if an applicant's PRA does, in fact, include all parts of the evaluation called for in paragraph (1)(ii), then this requirement will be satisfied.

(1)(iii)—Coolant Pump Seal Damage Evaluation

One commentor (CEC) states that paragraph (1)(iii) is superfluous, given the requirement for a plant/site specific probabilistic risk assessment (PRA) as specified in paragraph (1)(i).

Discussion

The rule requires applicants to evaluate reactor coolant pump seal damage and consequential added loss-of-coolant, following a small-break LOCA with loss of offsite power. The PRA might consider this area only peripherally, if at all, since its thrust is in the improvement of the reliability of core and containment heat removal systems. Accordingly, no change has been made in paragraph (1)(iii). However, this requirement will be satisfied if an applicant's PRA includes the evaluation called for in paragraph (1)(iii).

(1)(iv)—SBLOCA Probability Due to a Stuck-Open PORV

One commentor (CEC) argued that the PRA analyses required by paragraph (1)(i) would also include the analysis discussed in (1)(iv) in terms of the probability of small LOCA events. The commentor said, "the criteria for judging whether or not an improvement is to be made should, however, not rest with LOCA probabilities but rather with overall risk contribution and ultimately with the comparison of plant risk to a uniform safety goal."

Discussion

The WASH–1400 analysis for a PWR indicated that SBLOCAs contribute significantly to core melt probability. Furthermore, the TMI experience and subsequent analysis have shown that the likelihood of a SBLOCA due to a stuck-open PORV is greater than that assumed in WASH–1400. The purpose of this requirement is to determine whether this probability contributes substantially to the SBLOCA probability from all causes. If it does, an evaluation should be performed to ensure that this probability will be reduced by incorporating an automatic PORV isolation system, which will give assurance that the public health and safety is protected in the event of a stuck-open PORV. The Commission will retain this requirement. However, the requirement will be met if an applicant's PRA includes the analysis called for in (1)(iv).

(1)(v through xii)—Additional Studies

A. One commentor (CEC) states that all topics discussed in these paragraphs "could readily be considered in the PRA discussed in paragraph (1)(i)". Further, the commentor states that "it appears that many of the studies and criteria have a basis only in NRC staff judgment". Lastly, the commentor states that these studies, which are additional to the PRA discussed in paragraph (1)(i), "should be required only for those cases where the basic systems and related questions involved are shown to have a significant contribution to risk—in order to prioritize the work to be done and to conserve industry and NRC resources."

Discussion

In response to the first comment regarding paragraphs (1)(v through xii), it is noted that the specific paragraphs requiring study or evaluation by the applicant resulted from recommendations by the Bulletins and Orders Task Force. This Task Force conducted generic reviews of loss-of-feedwater and small break loss-of-coolant events on operating PWRs designed by B&W, Westinghouse and Combustion Engineering, and on operating BWRs.

These items were not explicitly included in the PRA in (1)(i) to ensure that the areas are specifically addressed. In some cases, the generalized PRA may not be extended to cover the required area, for example: paragraph (1)(vi), study to identify practicable system modifications to reduce challenges to and failure of relief valves in BWRs. However, if an applicant's PRA does, in fact, include the items called for in paragraphs (1)(v through xvii), then these requirements will be satisfied.

With regard to the second comment, it is the judgement of the Commission that potentially significant increases in plant safety could evolve from these studies and evaluations. At this time, the Commission is awaiting results of these studies and evaluations to determine whether certain plant modifications are warranted to improve plant safety.

In response to the last question regarding paragraphs (1)(v through xii), the Commission considers a risk assessment one of many tools which may be used to evaluate plant modifications and improvements. Direct evaluation, as considered in these paragraphs, is an equally valid tool.

In view of the foregoing discussion, no changes have been made in paragraphs (1)(v through xii) as a result of this comment. However, the Commission has made changes in wording to clarify the intent of paragraphs (1)(vii), (viii) and (ix). Proposed paragraph (1)(xi) has been deleted since a generic study applicable to all the affected applicants has been submitted for Commission review.

B. Another commentor (GE) noted that the NRC staff has agreed that the requirements specified in II.K.3.24 of NUREG–0718 should apply only to loss of offsite alternating current power.

Discussion

The Commission concurs and has revised paragraph (1)(ix) as follows to clarify its intent:

> Perform a study to determine the need for additional space cooling to ensure reliable long-term operation of the reactor core isolation cooling (RCIC) and high pressure coolant injection (HPCI)* systems, following a complete loss of offsite power to the plant for at least two (2) hours. (applicable to BWRs only) (II.K.3.24)
>
> *For plants with high pressure core spray systems in lieu of high pressure coolant injection systems, substitute the words, "high pressure core spray" for "high pressure coolant injection" and "HPCS" for "HPCI."

(2)(iii)—Control Room Design

One commentor (PSO) states that the text conflicts with the predicate given in § 50.34(e)(2) and suggests rewording (2)(iii) to read: "Provide a control room design that applies state-of-the-art human factor principles (I.D.1)." Two other commentors (SRW, CEC) suggested that the design be submitted for NRC "review" instead of "approval" since the latter has specific legal connotations in the engineering area. The suggestion was also made that "the rule should stipulate that the control room design consider state-of-the-art human factor principles, since direct application of all such principles may conflict with existing regulations."

Discussion

In response to the first comment, it should be noted that section (2) does not require a control room design prior to the granting of a CP, only sufficient information to ensure that an appropriate design will be submitted prior to fabrication or revision of panels and layouts. The Commission agrees with the other comments and has amended the text to read as follows:

> Provide, for Commission review, a control room design that reflects state-of-the-art human factor principles prior to committing to fabrication or revision of fabricated control room panels and layouts. (I.D.1)

(2)(vi)—Reactor Coolant System Vents

The commentor (CEC) notes that it may be well to review this requirement carefully on a plant specific basis to determine if any core cooling benefit can be identified; for some plants, reactor coolant system vents may offer no real benefit.

Discussion

The reactor coolant system high point vent requirement was developed to provide a means to eliminate gases that could inhibit core cooling. Since all plants have a potential to release non-condensible gases, this requirement applies to all plants. Although events in which gas venting would be required are highly unlikely, there does not appear to be an acceptable substitute at this time for those cases where venting may be needed. Consequently, the Commission is retaining this requirement, but has made a minor wording change for clarification. The paragraph now reads:

> Provide the capability of high point venting of noncondensible * * *

READEX FICHE

(2)(vii)—Radiation and Shielding Design

One commentor (PSO) suggested inserting the words "Provide a plan and submit a schedule to" at the beginning of the text to clarify its intent.

Discussion

The Commission does not believe this change is necessary since the language under (f)(2) clearly indicates that only sufficient information is required prior to granting a CP to demonstrate that the requirements, e.g., (2)(vii), will be met by the operating license stage. However, the Commission has substituted the word "materials" for "fluids" in the text since not only fluids are involved, and the words "TID 14844 source term" have been substituted for "highly" for clarification.

(2)(ix)—Hydrogen Control System

A. One commentor (OPS) requests clarification of the word "handling" in the requirement, "Provide a system for hydrogen control capable of handling hydrogen generated by the equivalent of a 100% fuel-clad metal water reaction."

Discussion

The Commission has substituted the words "that can safely accommodate" for "capable of handling" to clarify the intent.

B. Several commentors (OPS, Bechtel, GE, *W*, CEC, TVA) asserted that the 100% metal/water reaction requirement is too stringent and inconsistent with the value of 75% metal/water reaction in the proposed interim rule on hydrogen.

Discussion

While it is true that the TMI–2 accident produced less hydrogen than that assumed in the rule, and that the 100% requirement is greater than the 75% requirement in the proposed interim rule, the Commission finds that 100% is appropriate as a conservative bound for the design of plants not yet under construction. More specifically, the amount of hydrogen should not be tied to a given accident sequence (e.g., TMI–2), but rather a class of accidents which produce a large amount of hydrogen but hold promise of being recoverable, that is, for cooling to be re-established prior to what would otherwise be a substantial core melt-down. The proposed interim rule will be limited to accidents for which no or limited core melting takes place. The CP/ML rule considers potential accidents that are more severe than those considered in the interim rule. These severe accidents will be the subject of the degraded core rulemaking.

C. Another commentor (B&W) suggested that a maximum rate of hydrogen generation should be provided for the hydrogen control system.

Discussion

The hydrogen generation rates and release rates into the containment are a function of the reactor type, the accident sequence being considered, and the recovery (of cooling) schemes employed. Further, the effects of hydrogen generation rates and release rates (in terms of burning or detonation) are dependent on blowdown and steam-inerting characteristics in the containment. Thus, one maximum rate would be inappropriate and possibly overly conservative. Not having a maximum rate does not necessarily mean that the Commission expects detailed mechanistic analyses of hydrogen generation and release for a variety of sequences. Parametric analysis that adequately scopes the physical processes for the sequences under consideration would be acceptable.

(2)(x)—Relief and Safety Valves

Two commentors (Bechtel, B&W) pointed out that this requirement appears to elevate ATWS to the status of a design basis event.

Discussion

This is not intended, as the Commission is presently reviewing a proposed ATWS rule. Appropriate valve qualification requirements for ATWS can only be finalized after the Commission issues a final ATWS rule or decides that plants do not have to be designed to withstand an ATWS event. To clarify the intent of this requirement, it has been revised to read as follows:

> Provide a test program and associated model development and conduct tests to qualify reactor coolant system relief and safety valves and, for PWR's, PORV block valves for all fluid conditions expected under operating conditions, transients and accidents. Consideration of anticipated transients without scram (ATWS) conditions shall be included in the test program. Actual testing under ATWS conditions need not be carried out until subsequent phases of the test program are developed.

(2)(xii)—Auxiliary Feedwater System

A commentor (CE) suggests that the requirement to "provide an analysis of the effect on containment integrity and return to reactor power of automatic AFW system initiation with a postulated main steam line leak inside containment" be deleted since it would institute a regulatory requirement for an analysis of a condition normally assessed during the design of a safety-grade system, e.g., the auxiliary feedwater system. The commentor maintains that it is unnecessary to require this specific analysis in the rule.

Discussion

The Commission agrees with the comment and has deleted this part of the requirement because the regulations already require analyses of such systems (10 CFR 50.34(a)(4)). In addition, the term "safety-grade" has been deleted because that term is not explicitly defined in the regulations. With these changes, (2)(xii) now reads as follows:

> Provide automatic and manual auxiliary feedwater (AFW) system initiation, and provide auxiliary feedwater system flow indication in the control room. (Applicable to PWRs only) (II.E.1.2.)

(2)(xvii)—Primary System Sensitivity to Transients

A commentor (Gilbert), referring to this requirement, said "some statements of design criteria are so general as to be nebulous". Another commentor (B&W) objected to "sensitivity" and "reduce" in this requirement as not well-defined terms, making it difficult to know what features must be provided. A third commentor (PGE) indicated that the reference to NUREG–0718 action plan item II.E.5.2 appears incorrect.

Discussion

The requirements in 10 CFR 50.34(f) are intended to be general enough to allow a reasonable amount of flexibility in their interpretation. However, the Commission has deleted this requirement because it has not yet been sufficiently defined. After further study, appropriate action on this subject will be implemented.

(2)(xix)—Indication of Inadequate Core Cooling

A commentor (PGE) suggested the use of "and/or" instead of "and" in the last sentence since the present wording implies that all of the instruments must be provided. Another commentor (B&W) suggested deleting the examples of instrumentation that may be required.

Discussion

The commentor's reference to the "last sentence" is not clear since (2)(xix) has only one sentence. The Commission believes that the words "such as" clearly indicates that what follows are examples of instrumentation that may be required. However, the words "exit" and "core coolant flow rate" have been eliminated to better reflect the design requirements. As revised and renumbered (2)(xviii), the paragraph now reads as follows:

> Provide instruments that provide in the control room an unambiguous indication of inadequate core cooling, such as primary coolant saturation meters in PWR's, and a suitable combination of signals from indicators of coolant level in the reactor vessel and in-core thermocouples in PWR's

and BWR's. (II.F.2)

(2)(xxi)—Power Supplies

A commentor (PGE) noted "the requirement that motive and control components be designed to safety grade criteria is inconsistent with the applicable requirement of NUREG–0737 (which is referenced in NUREG–0718)."

Discussion

Paragraph (2)(xxi) has been renumbered (2)(xx) and part (B) has been revised to read:

> Motive and control power connections to the emergency power sources are through devices qualified in accordance with requirements applicable to systems important to safety.

(2)(xxii)—Auxiliary Heat Removal Systems

A commentor (PGE) noted that the reference to NUREG–0718 action plan item II.K.1.2 is incorrect.

Discussion

This reference has been corrected to II.K.1.22, and the paragraph has been renumbered (2)(xxi).

(2)(xxiv)—Anticipatory Reactor Trip

One commentor (B&W) indicates that a hard-wired, safety-grade reactor trip on loss of feedwater will be incorporated into the design of B&W plants; however, "B&W believes that the reactor trip upon turbine trip is disadvantageous." B&W states that "plants utilizing a once-through steam generator have the capability to run back on turbine trip without a reactor trip" and the "avoiding of a reactor trip for this event results in smaller perturbations in the primary system."

Discussion

Prior to the accident at TMI–2, B&W operating plants utilized a runback feature to avoid a reactor trip upon turbine trip. However, for each of these events, the PORV was opened to relieve reactor coolant system pressure. As part of the post-TMI–2 fixes to minimize challenges to the PORV, B&W-designed plants were required to lower the high pressure reactor trip setpoint from 2355 psig to 2300 psig and raise the PORV setpoint from 2255 psig to 2450 psig. These actions removed the runback capability for turbine trip events. In addition, B&W plants were required to install anticipatory reactor trips for loss of feedwater and turbine trip.

On applications currently undergoing OL review, such as Midland, the applicant has proposed certain design modifications that may reduce the probability of a small break loss-of-coolant accident (SBLOCA) caused by a stuck-open PORV.

These modifications include:

(1) A fully qualified safety-grade PORV;

(2) Safety-grade indication of PORV position;

(3) Dual safety-grade PORV block valves, capable of being automatically closed if a PORV malfunction occurs;

(4) A test program to demonstrate PORV operability;

(5) Installation of a safety-grade reactor trip on total loss of feedwater; and

(6) Resetting the PORV and high pressure reactor trip setpoints to their original values of 2255 psig and 2355 psig, respectively.

Should these modifications be found acceptable by the staff, the necessity of installing an anticipatory reactor trip upon turbine trip may be negated. However, until these or similar modifications are proposed and found acceptable by the Commission, the plant design must incorporate anticipatory reactor trips for both loss of feedwater and turbine trip.

No change has been made in paragraph (2) (xxiv) because of the comments. However, the Commission has modified the wording for clarification and deleted the words "safety grade" because this term has not been defined in the regulations. The paragraph has been renumbered (2)(xxiii) and modified to read as follows:

> Provide, as part of the reactor protection system, an anticipatory reactor trip that would be acutated on loss of main feedwater and on turbine trip. (Applicable to B&W-designed plants only) (II.K.2.10)

(2)(xxvi)—Recording Reactor Vessel Water Level

One commentor (GE) stated that this requirement should be deleted because task II.K.3.23 was not included in NUREG–0737.

Discussion

The TMI action plan, Table C.3, NUREG–0660, indicates that this issue is being covered in connection with TMI action plan item I.D.2, plant safety parameter display console; this latter item is identified in NUREG–0737. Specific console requirements for operating reactor licensees and OL applicants are under consideration by the Commission at the present time. The Commission considers that central water level recording is necessary for BWRs, and that it is appropriate to address such capability in a preliminary manner during the CP safety review. Consequently, this requirement will be maintained. However, the Commission has noted that the range over which the reactor vessel water level must be recorded as specified in the proposed rule is inconsistent with that specified in Regulatory Guide 1.97. Since either range is acceptable for the plants covered by the rule, the Commission has modified the requirement to allow that flexibility in its implementation. This paragraph has been renumbered (2)(xxiv) and changed to read as follows:

> Provide the capability to record reactor vessel water level in one location on recorders that meet normal post-accident recording requirements. (Applicable to BWR's only) (II.K.3.23)

(2)(xxviii)—ALARA Exposures

A commentor (Bechtel) noted that this requirement applies to the design basis of systems outside containment likely to contain radioactive material, rather than the development of leakage control and detection provisions intended by NUREG–0718, Item III.D.1.1.

Discussion

The Commission has renumbered the paragraph (2)(xxvi) and, for clarification, replaced the requirement with the following:

> Provide for leakage control and detection in the design of systems outside containment that contain (or might contain) TID 14844 source term radioactive materials following an accident. Applicants shall submit a leakage control program including an initial test program, a schedule for re-testing these systems, and the actions to be taken for minimizing leakage from such systems. The goal is to minimize potential exposures to workers and public, and to provide reasonable assurance that excessive leakage will not prevent the use of systems needed in an emergency. (III.D.1.1)

(3)(i), (ii), (iii)—Administrative Procedures and Quality Assurance

A. A commentor (Gilbert) stated that these requirements are a restatement of present 10 CFR requirements.

Discussion

Item (3)(i) has not been a previous requirement for CP reviews (recently, this has been identified as a requirement for OLs as Item I.C.5, NUREG–0737) nor have Items (3) (ii) and (iii), as stated in the proposed rule, been previous CP requirements.

B. Three commentors (S&W, NQA, TVA) noted that the inference of section (3)(iii) is that Appendix B of 10 CFR 50 is not sufficiently definitive. If this is the case, the proper place to provide such clarification or additional requirements is through Appendix B. It is the recommendation of the NQA Committee that paragraphs 50.34(f)(3) (ii) and (iii) be deleted from the proposed addition to the regulations because they do not clarify Appendix B and can only add confusion.

Discussion

10 CFR Part 50 Appendix B does set

forth basic QA criteria from which to develop a QA program. 10 CFR 50.34(a)(7) requires that the applicant describe its QA program in the PSAR and include a discussion of how the applicable requirements of Appendix B will be satisfied. Regulatory Guide 1.70 and the Standard Review Plan provide additional guidance on the extent to which this QA program should be described. The controls described in § 50.34(f)(3)(ii) and (iii) provide additional detailed criteria for proper implementation of Appendix B requirements.

C. Two commentors (NQA, Bechtel) noted that existing regulations contain provisions for the independence (separation) of those individuals who perform functions of attaining quality objectives from those individuals who verify compliance with requirements. Regulatory Guide 1.64 contains additional explanation for the intended independence for design verification purposes. The proposed addition to 10 CFR Part 50 goes beyond other regulations and regulatory guides and suggests the emphasis be placed on organizational independence rather than independence of personnel for objectivity and proficiency.

Discussion

The Commission agrees that Regulatory Guide 1.64 contains sufficient guidelines for independent verification of designs. Of particular concern to the Commission is the lack of sufficient independence of the organization responsible for performing checks, verifications, and inspections. Therefore, this aspect of an effective QA program is emphasized in the rule.

D. A commentor (NQA) also noted that (3)(iii)(B) "would require the entire body of quality assuring activities to be performed at the construction site. This would require massive upheaval and relocation to the construction site of not only top management, but also all support organizations."

Discussion

The objective of item B is to ensure that sufficient quality assurance and quality control activities are performed at the site rather than at corporate offices to provide closer management oversight and communication. To clarify the Commission's intent, (3)(iii)(B) has been modified to read:

> (B) performing quality assurance/quality control functions at construction sites to the maximum feasible extent;

E. The commentors (NQA, Bechtel) noted that (3)(iii)(C) is not clear whether quality assurance personnel should be involved in development of the procedures or should be assigned actions through the procedures.

Discussion

The Commission agrees that this item needs clarification to ensure a better understanding of the intent. Item (3)(iii)(C) has been modified to read as follows: "including QA personnel in the documented review of and concurrence in quality-related procedures associated with design, construction, and installation."

F. A commentor (NQA) noted that (3)(iii)(D) is "not clear in what is meant by QA requirements. If this refers to the requirements for quality assurance programmatic activities, the statement is acceptable; if it refers to requirements for the physical characteristics for classes of equipment, the statement is inappropriate."

Discussion

The Commission agrees that this requirement should be clarified. (3)(iii)(D) has been revised to read: "establishing criteria for determining QA programmatic requirements;"

G. A commentor (NQA) noted that "existing regulations now require the establishing of qualification requirements for personnel performing quality assurance activities. Regulatory Guides such as 1.58 and 1.146 add additional clarification concerning personnel who perform quality verification activities. It is not at all clear what additional requirements are intended" by Section (3)(iii)(E).

Discussion

The Commission acknowledges that the existing regulations do require, although not explicitly, the establishment of such qualification requirements. However, the Commission is retaining the requirements stated in (3)(iii)(E) to ensure that they are considered in the QA program. The word "minimum" has been deleted from this section to be consistent with Appendix B to 10 CFR Part 50.

H. The commentor (NQA) notes "that existing regulations would require staffing the quality assurance unit of the organization commensurate with its duties and responsibilities. It is not at all clear how the organization is staffed commensurate with its 'importance to safety'. Ordinarily, duties and responsibilities reflect the importance of the activity to be performed." Part (3)(iii)(F) "is not clear what is intended by the addition of 'importance to safety'."

Discussion

To clarify the intent, (3)(iii)(F) has been modified by deleting the phrase "importance to safety". Existing regulations do not specifically address the numbers of QA/QC individuals required for the design and construction activities associated with building a nuclear power plant. The size of the QA/QC organization should be dependent upon the quantity and type of quality-related activities that are on-going or projected during the design and construction of the nuclear facility.

I. The commentor (NQA) notes, relative to (3)(iii)(G), "that existing regulations contain requirements for preparation and maintenance of documentation including 'as-built' documentation. The problem concerning procedures may lie not in the requirements for them or their establishment, but in their implementation; i.e., procedures are available, but they may not be being followed."

Discussion

Existing regulations (i.e., Criterion VI, "Document Control" of Appendix B to 10 CFR Part 50) establish QA requirements for "* * * instructions, procedures, and drawings * * *" but do not address "as-built" documentation (e.g., as-built drawings). Because the controls imposed upon as-built drawings, which accurately reflect the actual plant design, have been abused in the past, it is the Commission's position that as-built documentation be addressed specifically by the QA requirements contained in the design and construction QA program. Therefore, (3)(iii)(G) has not been modified.

J. Three commentors (S&W, NQA, Bechtel) assert that the intent of (3)(iii)(H) is not clear. The NQA said that "if intent is to place quality assurance personnel on the design and analysis team, their independence may be compromised. Appendix B now requires that during design, the activities of design control and design verification are to be identified, defined, performed in accordance with written procedures by persons having proper capabilities and sufficiently independent of those who produced the design, so as to eliminate any conflict of interest. This being true, it is not at all clear what is intended by the proposed addition."

Discussion

The Commission agrees that existing regulations (i.e., Criterion III, "Design Control" of Appendix B to 10 CFR Part 50) already establish the requirements that verification of the adequacy of design be "* * * performed by individuals or groups other than those who performed the original design * * *" However, it is the Commission's intent that design documents (e.g., drawings, specifications, etc.) also be reviewed by individuals knowledgeable and qualified in QA/QC techniques to ensure that the documents contain the necessary QA/QC requirements (e.g., inspection and test requirements). For this reason, (3)(iii)(H) has not been changed.

(3)(iv)—Containment Penetration

Several commentors (OPS, Gilbert, *W*, CEC, TVA) centered on the asserted arbitrariness of the requirement for a 3-foot diameter penetration, the lack of technical justification, and the possibility that containment venting provisions may not provide a significant contribution to safety.

Discussion

The containment penetration size was selected so that it would be consistent with mitigation features designed to accommodate medium- and slow-rate pressure rises in containments that would otherwise have failed. Among the features considered were filtered vented containment systems and passive containment cooling systems. Rapid-rate pressure rises from hydrogen burns, for example, were excluded from consideration. The 3-foot penetration was determined to be a conservative penetration size that would not preclude the eventual installation of one of the aforementioned features. Of course, there is the possibility that such penetrations will not be needed, but that will be known only after the completion of the degraded core rulemaking. Therefore, the Commission has retained this requirement so as not to preclude later installation of containment venting systems, if required.

(3)(v)—Containment Design

A. One commentor (OPS) interprets the information requested on post-inerting and ignition systems as not allowing pre-inerting as a hydrogen control measure. Another commentor (CE) states that the level of detailed criteria requested by the Commission for hydrogen control obviates the use of alternative approaches to hydrogen control which may be developed in the future, and recommends eliminating the detailed criteria.

Discussion

The Commission is not limiting the options for hydrogen control by including criteria for post-inerting and ignition systems. Other systems (e.g., pre-inerting) may be proposed to meet the requirements stated in the proposed rule. Also, the level of detail in the criteria does not restrict design options for the post-inerting and ignition systems. The information requested on these systems is needed to ensure that operation of these systems will not adversely impact the safe shutdown of the plant.

B. A commentor (OPS) suggested that, to be consistent with (2)(ix), "requirement (3)(v)(A) should be modified to permit containment analysis to be based on the performance characteristics of existing systems and/or systems to be added during final design." The commentor also suggested rewording (3)(v)(A) to make the text easier to read. In doing so, the commentor suggested deleting the explicit requirement that the containment withstand the added pressure resulting from post-accident operation of the inerting system and inserted "the internal pressure shall be the maximum calculated pressure or 45 psig, whichever is greater."

Discussion

Part (3)(v)(A), as written, does not preclude consideration of the performance characteristics of either existing systems or systems that may be added during the final design. Furthermore, the suggested phrase "maximum calculated pressure" makes the requirement somewhat ambiguous. The Commission believes the present wording expresses the requirements clearly; therefore, no change has been made.

C. One commentor (TVA) maintains that the ten-percent uniformly distributed hydrogen concentration limit in (3)(v)(B) is unrealistically restrictive and should be resolved as part of the degraded-core rulemaking.

Discussion

The Commission believes that the ten-percent limit is appropriate as a conservative bound for the design of plants under construction. Accordingly, this requirement remains unchanged.

D. One commentor (GE) contends that the requirement (3)(v)(D) that the containment structure accommodate inadvertent full inerting is unnecessarily conservative. The commentor argues that a post-accident inerting system may be designed such that inadvertent inerting during plant operation could entail actuation of only part of the overall system, resulting in lower containment pressures. Hence, it was requested that the rule only address the maximum possible inadvertent inerting for the given system design. The commentor also requested relief on the containment test pressure criterion required for plants utilizing a post-inerting system based on the argument that full inadvertent inerting could be prevented.

Discussion

It is the Commission's position that human error needs to be considered in the inadvertent actuation of the post-inerting system and that partial inadvertent inerting cannot be assured in this case. Therefore, accommodation of inadvertent full inerting will be required. However, (3)(v)(D) has been renumbered (3)(v)(B) and revised such that all containment designs affected by this rule must have the capability to safely accommodate the pressure resulting from inadvertent actuation from a post-accident inerting system. This requirement will ensure that post-accident inerting remains a viable option until an applicant's comparative evaluation (See (1)(xii)) is completed and final selection of the hydrogen control system is made.

E. One commentor (OPS) proposed wording changes in (3)(v)(E) to make the text easier to read. Another commentor (Bechtel) suggested other changes "to avoid applying environmental qualification requirements to safety related systems and equipment which would not be needed to accommodate the conditions occurring following significant core degradation." Bechtel also proposed "to allow demonstration of qualification of these items by analysis and judgment and not mandate that these conditions be specified as design bases for the equipment."

Discussion

Equipment required for safe shutdown must perform its safety function in the environment to which it will be exposed during normal, abnormal and accident conditions. If particular equipment is not needed during or after a hydrogen burn, it need not perform its function in that environment, provided it can be shown that the failure of the equipment will not adversely affect any other needed safety function or mislead the operator. In general, the acceptable methods of demonstrating equipment performance are by testing or analysis based on partial test data. Such demonstration based on analysis or judgment alone may not be acceptable in all cases. No change has been made in (3)(v)(E) because of the comments; however, the words "and maintaining containment integrity" have been inserted to clarify that this consideration is meant to be included, and the requirement has been expanded to be applicable to all containment designs, irrespective of the selected method of hydrogen control.

Additional Changes in Requirements

As a result of its consideration of the comments from the public, the Commission has deleted paragraph (2)(xvii) and changed the wording of several paragraphs of the proposed rule, as discussed above.

In addition, the Commission has modified the wording of several more paragraphs, as shown in the final rule, to clarify their intent, and has deleted paragraphs (1)(xi) and (2)(xxv) of the proposed rule for the reasons discussed below:

1. The requirement proposed in paragraph (1)(xi) is no longer needed since a generic study applicable to all of the affected applicants has been submitted for NRC staff review to demonstrate that the BWR core remains covered for anticipated transients combined with the worst single failure.

2. The requirement in paragraph (2)(xxv) concerning the type of pressure-operated relief valve is too specific and the purpose of the requirement is adequately covered in paragraph (2)(x).

Deletion of the three paragraphs cited above has resulted in appropriate renumbering of the succeeding paragraphs in the final rule.

Finally, the Commission has added a requirement (paragraph (1)(xii)) for a comparative evaluation of alternative hydrogen control systems and a requirement (paragraph (3)(v)(B)) that all containment designs must have the structural capability to safely accommodate the pressure resulting from inadvertent actuation of a post-accident inerting system. These new requirements ensure that the post-accident inerting method of hydrogen control remains a viable option until final selection of the method for hydrogen control is made.

Substance of the Rule

This rule, which has been drawn from NUREG–0718, Licensing Requirements for Pending Applications for Construction Permits and Manufacturing License, March 1981, imposes new safety requirements on pending construction permit and manufacturing license applications. The Commission has determined that these requirements must be met by all applicants for construction permits or manufacturing licenses whose applications are pending as of the effective date of the rule. Specifically, these applicants are: Duke Power Company (Perkins Nuclear Station, Units 1, 2 and 3), Houston Lighting & Power Company (Allens Creek Nuclear Generating Station, Unit 1), Portland General Electric Company (Pebble Springs Nuclear Plant, Units 1 and 2), Public Service Company of Oklahoma (Black Fox Station, Units 1 and 2), Puget Sound Power & Light Company (Skagit/Hanford Nuclear Power Project, Units 1 and 2), and Offshore Power Systems (License to Manufacture Floating Nuclear Plants). It should be noted, however, that there are some elements in the TMI Action Plan (NUREG–0660), not included in NUREG–0718, that have not yet been acted upon by the Commission. These are items that the Commission has directed be subject to further study before taking approval action. It is possible, therefore, that some of these items will be approved for implementation prior to completion of the licensing review of the pending construction permits or manufacturing license. In that event, such items might be added to this rule. The Commission is aware, however, that the applications covered by this rule have already been substantially delayed and the facility designs may be further advanced than normally expected at the construction permit and manufacturing license review stage. The Commission will take this into account as further requirements are considered. Full opportunity for public comment will be provided if additional requirements are contemplated which would apply to these applications.

While this rule contains the basic requirements set out in NUREG–0718, it does not incorporate the entirety of the document. In particular, the rule does not contain the detailed criteria contained in Appendix B to NUREG–0718 for satisfying many of the requirements. To have included such detail would have resulted in a rule that would be excessively detailed and restrictive.

In addition, this rule does not identify, as does NUREG–0718, the items from the TMI–2 Action Plan, NUREG–0660, that are considered either not applicable to pending construction permit and manufacturing license applications, or to be requirements of the type customarily left for the operating license stage. However, the Commission has reviewed NUREG–0718, as revised[*] to account for the changes made between the proposed and final rule, and has concluded that the list of TMI-related requirements contained therein can provide a basis for responding to the TMI–2 accident. Applicants may, of course, propose to satisfy the rule's requirements by a method other than that detailed in NUREG–0718, but in such cases must provide a basis for determining that the requirements of the rule have been met.

Based upon its extensive review and consideration of the issues arising as a result of the Three Mile Island accident, the Commission has decided that pending applications for a construction permit or manufacture license should be measured by the NRC staff and Presiding Officers in adjudicatory proceedings against the existing regulations, as augmented by this rule. It is the Commission's view that this new rule, together with the existing regulations, forms a set of regulations, conformance with which meets the requirements of the Commission for issuance of a construction permit or manufacturing license, with one exception. For the manufacturing license application, the hydrogen control provisions of the existing regulations, namely, 10 CFR 50.44 and Criterion 50 of Appendix A to 10 CFR Part 50, together with the hydrogen control provisions of the new rule (subsections (1)(xii), (2)(ix), and (3)(v), are to be considered necessary but not necessarily sufficient. That is, the issue of the sufficiency of the hydrogen control measures required by these provisions may be considered in the manufacturing license proceeding, and the Commission may decide to impose additional requirements. Further studies in the area of hydrogen control, containment loading, and mitigation may, at some later date, resolve this issue sufficiently so that it may be addressed by further rulemaking and removed from the pending manufacturing license proceedings.

Some of the proposed rule's provisions deal with studies to be conducted by the license applicants. The Commission intends to impose license conditions upon all permits and licenses covered by this rule which will require submittal of these studies to the NRC for review and appropriate action. The license conditions will specify due dates or may require that studies be submitted prior to hardware procurement or other construction events.

Conforming Changes to 10 CFR Part 2. Several conforming changes have been made to 10 CFR 2.764. Because these amendments are non-substantive, notice-and-comment procedures are unnecessary. Although these amendments could be made immediately effective, they will be effective on the same date as the Part 50 amendments in this notice.

Views of Chairman Palladino and Commissioners Ahearne and Roberts. The Commission decision to establish a rule for pending construction permits and manufacturing licenses is based on the view that nuclear plants in the early stages of construction—where capital investment is relatively small—are most amenable to a generic regulatory approach. On the other hand, the Commission believes regulatory flexibility is needed for nuclear plants that are operating. This flexibility recognizes that operating plants—which represent a substantial capital investment—often need case-by-case review to determine the best way to make changes deemed necessary for public health and safety. Therefore, the Commission does not agree with Commissioner Bradford's views on this subject.

It is the Commission's view that this new rule, together with the existing regulations, is sufficient for issuance of a limited number of manufacturing licenses. As stated in the "Substance of the Rule" section above, however, the Commission may decide to impose additional requirements, and the sufficiency of the hydrogen control measures mandated by this rule and the existing regulations will remain a litigable issue in the manufacturing license proceeding pending further rule making based on the results of future studies. For the sake of clarity, it should be stated that for the construction permit proceedings covered by this rule, the existing regulations together with this new rule are both necessary and sufficient as regards hydrogen control measures. If the results of future studies warrant, the hydrogen control issue may, by further rulemaking, be removed from manufacturing license proceedings.

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[*] NUREG–0718, Revision 2, dated January 1982. NUREG documents may be purchased through the NRC/GPO sales program by writing to U.S. Nuclear Regulatory Commission, ATTN.: Sales Manager, Washington, D.C. 20555 or by calling (301) 492–9530.

Additional Views of Chairman Palladino (with which Commissioner Bradford agrees). The CP/ML rule approved by the Commission does not require consideration of instability (buckling) for containment loading due to inadvertent inerting.

The staff recommended that the Commission include buckling in the CP/ML rule. It is the staff's opinion that prudent rule development would require that ASME code requirements for buckling be met for all high likelihood events that might affect the containment, such as inadvertent inerting. I agree with the staff's opinion on this requirement.

Separate Views of Commissioner Gilinsky. I approve this rule in its entirety as it applies to pressurized water reactors (PWR's) with standard large containments, which includes most such reactors. I also approve the rule as it applies to other reactors with the following exceptions:

I disapprove the hydrogen control provisions of the rule as they apply to General Electric Mark III plants and Westinghouse ice condenser plants, both of which have relatively smaller and weaker containments than standard PWR's, and are therefore less able to withstand possible post-accident hydrogen burns. Substantially stronger containments should have been required in both cases.

Under the rule, the Commission has permitted Mark III plants whose construction has not yet begun to protect against post-accident hydrogen burns by installing, among other means, essentially the same hydrogen control systems—electrical igniters intended to burn excess hydrogen in a controlled manner—that are being added to similar plants which are nearing completion.

The Commission has taken a more tentative approach in the case of PWR's with ice condenser containments. The rule provides that the hydrogen control requirements for these plants are to be "considered necessary but not necessarily sufficient," and that the sufficiency of these requirements may be litigated in the Manufacturing License proceeding. The Commission is apparently less sure about the efficacy of current hydrogen control systems in this case. The Commission states that further studies "may, at some later date, resolve this issue" so as to remove this issue from the proceeding by rulemaking.

The Commission does not have a technical basis for drawing a distinction in this instance between the unbuilt Mark III plants and the unbuilt ice condenser plants. Both types of plants have relatively weak containments, and stronger containments are needed in both cases. The Commission should have required such stronger containments now.

For the plants nearing completion, compromises had to be made to accommodate the realities of the plants' construction—in many cases the containment was already completed. No such compromises needed to have been made in the case of plants whose construction has not yet begun.

It is true that redesign of the containment and associated features would have been necessary and that this would have taken time. But we had the time. It is now almost three years since the Three Mile Island accident demonstrated that large hydrogen burns were possible and that such burns could generate pressures which exceed the capabilities of the smaller and weaker containments. It is unfortunate that the Commission did not face up to this issue earlier.

Separate Views of Commissioner Bradford. The Commission recently declined to consider a proposed rule (SECY-81-244) that would have imposed many of the lessons learned from the Three Mile Island accident on NRC licensees in regulation form. The arguments advanced against this approach were that such a regulation would reduce needed flexibility and would encompass too many different subjects within the scope of one rule. While both of those arguments were probably wrong in the context in which they were advanced, they apply precisely to the rule being promulgated here.[1] No legal or logical reason can be advanced that favors the imposition of this rule on the licensing process while weighing against the imposition of the similar rule on the operating reactors. The only possible governing principle is the convenience of the nuclear industry, which the Commission has accommodated completely in both situations.

The Commission has already instructed the staff to use specific provisions in this rule as the basis for its position in contested construction permit cases. What it is now providing is that intervenors who wish to challenge the adequacy of some of the provisions proposed here will not be able to do so. In effect, the Boards are being required to rule against them without hearing their evidence.

This authoritarian obsession with the avoiding of public challenge has been a source of continuing trouble for nuclear power over the last decade. That it should now be applied to limit the lessons to be learned from the accident that it helped to cause provides an unsettling indication that the NRC may be returning to its former bad habits.

Additional Views of Commissioner Ahearne. Lest silence be taken as assent, I note that I strongly disagree with Commissioner Bradford's opinions of the reasons for declining to make SECY-81-244 into a rule, the reasons for making SECY-81-20D into a rule, the lessons learned from the fire protection rule, and of the NRC's approach to public hearings.

Further Additional Views of Commissioner Ahearne. The NRC staff "suggests that the Commission consider the desirability of further modifying section (3)(v)(B)(1) on page 81 to require that instability be considered in designing the containment to withstand inadvertent inerting." (P. 3, Secy-81-631, November 4, 1981)

The basis for this recommendation is a November 2, 1981 NRR memorandum "Containment Instability." (Enclosure 2 to Secy-81-631) In this memorandum, the reasons are given to be the following:

—the exemption for instability consideration under the inadvertent inerting

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[1] In the context of the rejected rule for operating reactors, the Commission should have learned the real consequences of this kind of "flexibility" from its experience with fire protection. A similarly informal approach was attempted with the licensees following the 1975 Browns Ferry fire. As the very generous 1980 deadline approached, it was clear that many of the licensees had taken advantage of the absence of a firm rule to ignore actions that the NRC staff thought important. As a result, the Commission was finally forced to put its fire protection requirements in regulation form, meanwhile extending the deadlines out to a ludicrous seven or eight years for many plants.

With regard to the point that a single rule can encompass too many subjects, it is worth remarking that the danger is much less when the parties primarily affected by the rule are the licensees. They have the financial, legal, and technical resources to comment extensively on a complex rulemaking to such an extent that the Commission will be fully aware of the consequences of its rule before imposing it. Furthermore, the operating reactor rule provided for exemptions to be granted as necessary. The rule promulgated here contains no similar provision.

> condition may limit the usefulness of the rule by presenting the opportunity for technical challenges to future operation of plants choosing post accident inerting systems.
>
> —ASME Code Service Limit A stress criteria are therefore required in the rule to assure with high confidence that inadvertent inerting occurring at any time in the life of a plant, or several times for that matter, would not result in degradation of the containment structure.

This staff suggestion was discussed at a meeting with the NRC staff, described in a December 17, 1981 memorandum by Dr. B. D. Liaw "NTCP/ML Rule Containment Structural Requirements." Dr. Liaw makes the following points:

> —* * * the question centered around whether or not the *Code* buckling criteria needed to be considered for the inadvertent inerting conditions during normal operations.
>
> —* * * the staff was asked whether or not there was a compelling technical reason to require that the code buckling criteria be considered. Or, to rephrase it, whether or not the containment shell of both ice condenser and Mark III plants would buckle under the inadvertent inerting and test conditions.
>
> —* * * The general consensus was that the containment would not buckle for the following reasons * * *
>
> —* * * the Code has a factor of safety of 3 to 4 * * *
>
> —* * * the Code limits are established for external pressure and uniaxial compression * * *
>
> —* * * the case of discussion (here) is for internal pressurization that induces tension in most parts of the shell * * *
>
> —* * * there was an agreement (by NRC staff management and technical personnel) that the question is really not a technical issue whether the containment shell would buckle under inadvertent inerting and test conditions.

As I wrote in my December 17th memorandum to my fellow Commissioners ("CP/ML Rule Containment Structural Requirements"):

> I do not see the analytic case for requiring a buckling criterion * * *. I do not believe the Code buckling criterion is needed for inadvertent inerting. On the other hand, (t)his criterion also does not come close to meeting the detonation pressure (if there were a hydrogen explosion). If the Commission's position is that all containments should have an estimated pressure capability of X, we should address that issue directly.

I believe we must develop regulatory requirements based on reason. If we are substantially uncertain about an issue, we should leave it open to be debated in individual cases.

Regulatory Flexibility Statement. In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission hereby certifies that this rule will not have a significant impact on a substantial number of small entities. This rule affects five applicants for construction permits and one applicant for a manufacturing license. These applications are for permits or a license for plants that do not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act in the Small Business Size Standards set out in regulations issued by the Small Business Administration at 13 CFR Part 121.

OMB Regulatory Requirements Clearance. The application requirements contained in this final rule affect fewer than 10 persons (applicants) and, therefore, are not subject to Office of Management and Budget clearance as required by Pub. L. 96-511.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and Sections 552 and 553 of Title 5 of the United States Code, the following amendments to Parts 2 and 50 of Title 10, Chapter I, Code of Federal Regulations are published as a document subject to codification.

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47 FR 4490
Published 2/1/82
Effective 2/1/82

10 CFR Part 2

Amendment To Provide Exception From Procedural Rules for Adjudications Involving Conduct of Military or Foreign Affairs

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Commission is readopting that part of its "Rules of General Applicability" for the conduct of adjudicatory proceedings in 10 CFR Part 2 which provides an exception from those rules for adjudications involving the conduct of military or foreign affairs functions. The rule, 10 CFR 2.700a, has been restated to reflect the Commission's intent that the exception it provides may be applied to pending proceedings. This exception permits the Commission to exercise greater flexibility in fashioning procedures for proceedings involving military or foreign affairs functions pursuant to the exception stated in the Administrative Procedure Act (APA) at 5 U.S.C. 554(a)(4).

EFFECTIVE DATE: February 1, 1982.

FOR FURTHER INFORMATION CONTACT: Marjorie S. Nordlinger, Office of the General Counsel, Nuclear Regulatory Commission, Washington, D.C. 20555, phone 202-634-3214.

SUPPLEMENTARY INFORMATION: The Commission has readopted that part of its rules governing procedure for adjudications in subpart G of 10 CFR Part 2 which provides an exception from those rules for proceedings to the extent that there is involved the conduct of military or foreign affairs functions. In readopting that exception stated at 10 CFR 2.700a, the Commission has explicitly provided that the rule shall apply to Nuclear Regulatory Commission (NRC) proceedings in progress where hearings have already been requested or ordered.

On September 30, 1981 the Commission published notice of its intent to reconsider 10 CFR 2.700a. 46 FR 47799. The Commission specifically requested comment on the exception itself and regarding the issue of whether the rule, if readopted, is applicable to pending proceedings. *Id.* at 47800.

Five commenters responded to the Commission's notice. They are: Americans for Democratic Action (ADA); Natural Resources Defense Council (NRDC); Ms. Suzanne Sherbondy, an individual who is affiliated with NRDC; the Department of Energy (DOE); and Nuclear Information and Resource Service (NIRS).

The Department of Energy favored retention of the rule and its application to pending proceedings. DOE supported this view with specific reference to several facilities regulated by NRC where military functions of the United States are involved and thus where procedural flexibility is desirable. In DOE's view the Commission correctly applied its rule to a pending proceeding and reconsideration was not warranted. ADA commented that the rule was unnecessary because the APA exception which it duplicates is already applicable to NRC proceedings. ADA commented further that on the facts stated by NRDC it believed the rule was "probably not applicable" to the Erwin matter and would be likely to be similarly misapplied in the future. The three other commenters flatly opposed the rule, taking the further position that if retained it should be clarified and limited in application and in any event should not be applied to pending matters. NIRS recommended specifically that the rule should require as a condition for application that "the commercial plant in question has, under rare and unusal circumstances, direct military involvement, such as may be the case in time of war; or, if the Department of State or the President should deem a certain activity necessary to conduct foreign affairs at a particular point in time."

On consideration of these comments the Commission has not been persuaded to repeal its rule or to bar its application to the already noticed hearing on NFS Erwin's license amendment which has been stayed by order of the United States Court of Appeals for the District of Columbia, in *Natural Resources Defense Council* v. *Nuclear Regulatory*

Commission, Nos. 80–1845 and 1846. Accordingly, the Commission readopts the rule as stated to apply to pending proceedings.

Readoption of the Rule

The essential point made by the Commission in originally adopting the rule was that doing so explicitly provided the administrative flexibility intended for any or every government agency when military or foreign affairs of the United States are involved in administrative adjudications. Two arguments that go to the merits of NRC's adopting such a rule have been made by commenters opposing the rule: (1) That NRC has no military or foreign affairs functions to which it is applicable, (2) that the rule is unnecessary because it duplicates and exception already available in the Administrative Procedure Act. Also, some commenters suggested that if NRC should decide to include the APA exception in its rules, some restrictive language going beyond the bare language of the APA should be included.

Regarding the first, as DOE has argued in its comments, NRC licensing actions at several facilities present at least the possibility of involvement of military functions of the United States. NRC licensing proceedings may, depending on the nature of the licensed activity, "involve" military or foreign affairs functions even though licensing itself is not actually regarded as a military or foreign affairs function. In the NFS Erwin matter the Commission has specifically decided that military functions are involved. Although export decisions are not subject to the agency's adjudicatory process, regulatory proceedings at domestic facilities admit the possibility of foreign affairs involvement, for example, where facilities are subject to International Atomic Energy Agency (IAEA) inspection or where materials in transit are covered by our rules. See e.g., 10 CFR Part 75.

Moreover, whether or not it now appears that NRC has regulatory resonsibilities involving military or foreign affairs functions, it is entirely reasonable for the Commission to incorporate in its rules the full flexibility provided by the APA and made applicable to its proceedings by Section 181 of the Atomic Energy Act of 1954, as amended, 42 U.S.C. 2231. This is true so that it will be clear that this exception is applicable in the event of a military or foreign affairs involvement.

Regarding the second argument, we concur with both ADA's statement that the rule duplicates a provision of the APA and ADA's implication that therefore it not only is but has been available to the Commission. Nonetheless, in order to clarify that this is the case and to have all rules including exceptions for adjudicatory procedures available in one place, the Commission adheres to the course of retaining rule § 2.700a in its rules of practice.

Just as there can be no serious doubt about the appropriateness of the Commission's incorporating an APA provision into its own rules of practice, there can be no doubt about the appropriateness of doing so *verbatim*. The Commission does not therefore accept some commenters' recommendations to incorporate in the Commission's rule limitations that go beyond the bare language of the APA and arguably nullify its intent that wherever *military* functions are involved the rule is applicable. Had Congress intended this rule to be limited to time of war it may be presumed to have so stated.

Doubtless in the course of application of the rule the Commission will explore the bounds of the rule case by case as the subject matter requires. This process is clearly preferable to imposing unintended limits at the threshhold.

Application to Pending Proceedings

With the exception of NRDC no commenter provided views that addressed the applicability of the rule to a pending proceeding or to the NFS Erwin proceeding as a pending proceeding. Those who commented negatively did so essentially on the basis that the NFS Erwin proceeding does not involve military functions. As we stated above, the Commission has decided that issue otherwise and the United States Department of Energy concurs in that view.

NRDC reiterated the position that it has taken from the first that application of the rule is impermissible as it will prejudice NRDC's rights in an ongoing matter. As it argued in its briefs before the D.C. Circuit which were submitted as comment in this rulemaking, NRDC finds prejudice in the loss of expected rights to discovery the cross-examination. Presumably NRDC would argue on this basis that the rule may not legally be applied to any pending adjudication.

The Commission's position is that NRDC's view of the law on application of procedural rules to pending matters is erroneous. Nonetheless, the issue is before the Court of Appeals for the D.C. Circuit and will be resolved there. In that proceeding the Commission has briefed its response to NRDC's legal arguments. It is sufficient here to state that in the Commission's view a change in hearing format will not preordain the outcome of the NFS Erwin proceeding and will work no prejudice on NRDC in that proceeding.

As a general matter, the Commission believes it would be acting unwisely to preclude its use of the military or foreign affairs exception in any adjudication now pending in the event that a matter of military or foreign affairs were to become implicated. Such action would be contrary to Congressional intent. Congress indicated that the exception should be exercised by providing that *in any agency* those matters qualifying for the exception *are excluded* from coverage of the APA adjudicatory rules.

Good Cause for Immediate Effectiveness

The Commission's readoption of 10 CFR 2.700a in the proposed form including a slightly modified provision permitting application to pending proceedings is made effective on publication for the following reasons.

First, the rule is not substantive but is procedural in nature. Second, the only persons who would be affected by immediate effectiveness of the rule are the parties in the NFS Erwin proceeding. Those parties have long been on notice of the Commission intentions and immediate effectiveness imposes no additional burden on them.

Separate and Additional Views of Commissioners

1. Separate Views of Commissioner Gilinsky

The NRC does not need this rule. This agency and its predecessor, the AEC, have functioned for more than twenty-five years without such a rule, with no descernible detriment to the military and foreign affairs matters which have been subject to their jurisdiction. Our regulations are adequate to protect classified information in our proceedings; our review of exports is already statutorily exempt from the adjudicatory provisions of the Administrative Procedures Act. It is clear that this rule was proposed in 1980 [1] solely to limit the public inquiry into the Commission's decision to relax the material accounting standards applicable to the NFS Erwin facility, which is involved in the production of nuclear fuel for the Navy. This decision followed the discovery that the Erwin facility was unable to satisfy the NRC material accounting requirements for potential bomb material.

There is little question that if the NFS Erwin facility had been handling nuclear material intended for civilian use its license would have been revoked. However, because the operations of this facility are ultimately dictated by the needs of the Navy, without regard to whether or not NRC requirements are met, the NRC staff suggested transferring responsibility for the oversight of this facility to the Assistant Secretary for Defense Programs at the Department of Energy. I agreed with the staff's suggestion; it would have ensured that DOE, which has effective control over the operations of the facility, would also have responsibility for the manner in which it is operated. This would have brought the NFS Erwin plant under the same system of oversight which applies at other national security facilities. The Commission decided on another course. It relaxed the applicable material accounting requirements to a level the facility was thought to be able to meet. This retained the appearance of compliance with NRC safeguards requirements and masked the fact that real control over the plant had been transferred to DOE.

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[1] Federal Register, Vol. 45, No. 130, p. 45253, July 3, 1980.

After making its decision, the Commission offered an opportunity for a hearing. When one was requested by the Natural Resources Defense Council, the Commission appears to have belatedly realized that the adjudicatory hearing normally held in these circumstances would subject its decision to too searching a review. It then attempted, without providing notice or an opportunity for comment, to adopt a rule excepting military and foreign affairs functions from the usual adjudicatory procedures, which it intended to apply retroactively to the NFS Erwin case. That effort floundered on the implausibility of arguing that the adoption of a military and foreign affairs exception rule was itself a military or foreign affairs matter exempt from the normal rulemaking provisions of the APA. Although the Commission has now remedied that legal defect, the courts may still look askance at its efforts to apply this rule retroactively to the NFS Erwin case to deprive the parties of their procedural rights.

More importantly, in its haste to deal with the NFS Erwin hearing, the Commission has not considered where and how to apply this rule. For example, would a hearing to license a waste disposal facility be subject to this rule because some of the waste is of military origin? The rule should not be applicable to such a case, but the test of the rule does not preclude such application. At a minimum, the rule should be modified to make it clear that the normal adjudicatory procedures may only be waived where such a waiver is essential and conduct of military or foreign affairs functions is directly at issue.

One of my reasons for arguing, a year and a half ago, that the Department of Energy should assume authority over NFS Erwin was that the NRC's efforts to bend its requirements in order to accommodate DOE would tend to undermine NRC's regulatory process as it applies to other facilities. This is, in fact, what I see happening. The right course is still to transfer oversight authority over this plant to the Department of Energy so that responsibility can be joined with authority.

2. Separate Views of Commissioner Bradford

Once again the Commission is taking action that its attorneys had, back when they still had freedom of choice in the matter, advised strongly against.[2] While the agency now implicitly acknowledges the illegality of its original pretense that the promulgation of a military affairs exemption is itself a military function,[3] that bizarre notion's day in the sun still sets the tone for this rulemaking. Three issues remain: (1) Do we need the military and foreign affairs exemption, and, if so, the one proposed? (2) Does the Erwin matter involve a military function? (3) Should the rule apply retroactively?

We obviously do not "need" this rule for any wise purpose. The agency has functioned smoothly for decades, during which the country has fought some wars, considered others and probably deterred a few more without the rule's absence being noticed at all. Nor does anything in the present state of the world seem likely to make its absence the missing horseshoe nail of some future conflict.[4]

Nonetheless, comment having been sought, the Commission has the power to adopt this rule, and even to do so in the form and manner proposed. Still, the fact that alcoholics have the right to buy liquor does not make them wise to do so, especially in the absence of substantial restraining forces. Despite the clear penchant for overindulgence that the NRC has demonstrated in this area, no such restraints on the use of the military functions exemption are imposed. Given what its brief history and its present use reveal about the temptations that it offers, the limits proposed by the commenters should have been adopted.

A more serious legal question is whether this exemption is properly applied to NRC regulation at Erwin. The Erwin facility has as its sole purpose the processing of highly enriched uranium for fuel in the nuclear submarine program. However, it is privately owned and operated, and its output goes to another private company before being transferred to the Navy. The employees are all civilians. The contractor is the Department of Energy (not Defense). The DOE involvement in nuclear matters is the *civilian* jurisdiction deliberately created by the Congress in the Atomic Energy Act of 1946, reaffirmed once in the Atomic Energy Act of 1954, again in the Energy Reorganization Act of 1974 and again in the 1978 legislation creating DOE. Throughout these 35 years, the Atomic Energy Commission/DOE nuclear jurisdiction has been civilian until the point at which a product is turned over to the military. Thus, Erwin is clearly on the civilian side of the line.

The civilian nature of the function at issue here is reinforced by the fact that the Navy's fuel supply is not in jeopardy. Neither classified information nor DOE submissions contravene this point. The conditions for Erwin's continued operation may be at issue (including whether a new facility should replace it), but the fueling and running of the submarines are not. It is the submarines and the security of their fuel that are the military function. The regulation of the conditions surrounding but not essential to these functions is emphatically non-military. To misunderstand this is to misunderstand the Congressional motive in establishing civilian control of nuclear matters in the Atomic Energy Act and in narrowly circumscribing the military affairs functions exemptions.[5] Furthermore, this blurring of the distinction invites similar sleight-of-hand in many other contexts to shield from adjudicatory inquiry or from the Administrative Procedue Act chains of defense procurement activities that are many steps removed from any military functions.

The final question, if our regulation at Erwin is found to be a military function, is whether the NRC should or can apply its new rule in a proceeding originally offered under a different set of rules. It is here that the agency continues to ignore aspects of the advice furnished by its two legal offices from March until June, 1980.

The first half of the question is easy—the Erwin proceeding is of precisely the sort to which adjudicatory processes are essential. The extent to which the public is adequately protected by the measures that the Commission now employs at the Erwin facility flows directly from narrow questions of fact having to do with, for example, statistical and measuring capabilities, potentials for theft, past shortcomings, and the costs and benefits of a new facility.[6] The wisdom of continuing the 1979 relaxation in light of DOE's failure to move toward an alternative facility is very much in doubt and rests entirely on our capability to detect and prevent diversion of material that can be used to make atomic bombs. The ultimate conclusion may be one of policy,[7] but it will be based heavily on material facts that are very likely to be contested. Therefore, the NRC's own interest in a reliable record is best served by a hearing, involving discovery and cross-examination, of the type that it first offered to NRDC in February, 1980.[8]

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[2] *Nuclear Fuel Services, Inc.*, 11 NRC 799, 809, Note 3 (June, 1980). I should note that making internal agency legal advice public is not our normal practice. Indeed, the June, 1980 decision represents the only time in the more than four years of my term that I have done so. I took the step on that occasion only because the Commission, immediately *after* its Secretary had announced its vote, extracted a public statement from its General Counsel that its action had been "legal" despite his previous advice putting that proposition at least very much in doubt.

[3] *Ibid.* pp. 809–810.

[4] The conduct of foreign affairs will also continue uninterrupted without this rule. NRC export licensing decisions are already exempted from the Administrative Procedure Act by statute.

[5] Legislative History of the Administrative Procedure Act. S. Doc. No. 248, 79th Congress 2d Sess. 199 and 287 (1946).

Since I have concluded that an adjudicatory hearing should be offered by choice, I need not decide whether the law requires us to do so. The NRDC will clearly be disadvantaged without adjudicatory procedures, for the essential information is in the possession of parties who have shown themselves to be reluctant to share it. The NRC has always viewed cross-examination and discovery as substantive rights. Whether the NRC may now inflict substantive disadvantage by alleging a lack of prejudicial reliance in a proceeding in which it has managed to stall off significant progress for two years is for the courts to decide. Such a course is certainly unwise and unfair. It would not be cause for regret if it turns out also to be illegal.

3. Additional Views of Commissioner Ahearne

I disagree with many of Commissioner Bradford's comments. To repeat points which have been made in the past: The General Counsel did advise that the Commission's actions were legal,[9] the fuel supply for the Naval Nuclear Propulsion Program is directly affected,[10] and although the Commission offered a hearing, it did not specify an adjudicatory hearing and a majority agreed that under the circumstances a modified legislative hearing before the Commission was more appropriate than a formal adjudicatory hearing before a Licensing Board.[11]

Regulatory Flexibility Statement

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission hereby certifies that this rule change would not have a significant economic impact on a substantial number of small entities. The rule change would affect the Commission's procedures by permitting informal procedures where military functions of the United States are involved. Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and Sections 552, 553, and 554 of Title 5 of the United States Code, notice is hereby given that the Commission is reconsidering its now stayed adoption of the following amendment to Title 10, Chapter 1, Code of Federal Regulations, Part 2.

Paperwork Reduction Act Statement

Pursuant to the provisions of the Paperwork Reduction Act of 1980 (Pub. L. 96–511), the NRC has made a determination that this proposed rule would not impose new recordkeeping, information collection, or reporting requirements.

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47 FR 9983
Published 3/9/82
Effective 4/8/82

Correction 47 FR 17797

10 CFR Parts 1 and 2

Implementation of Commission's Delegation of Authority To Determine Whether There Have Been Significant Changes in Operating License Applicant's Activities or Proposed Activities Since the Construction Permit Antitrust Review

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations to incorporate final procedures implementing the Commission's delegation of authority to make the "significant changes" determination to the Director of Nuclear Reactor Regulation or the Director of Nuclear Material Safety and Safeguards, as appropriate. The "significant changes" determination, mandated by Section 105c(2) of the Atomic Energy Act of 1954, as amended, is whether there have been changes of antitrust significance in an operating license applicant's activities or proposed activities that have occurred subsequent to the antitrust review conducted in connection with the facility construction permit.

EFFECTIVE DATE: April 8, 1982.

FOR FURTHER INFORMATION CONTACT: Argil Toalston, Antitrust and Economic Analysis Branch, Division of

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[6] In this context, I should note that my 1979 concurrence in the original relaxation of limits at Erwin was premised on a good faith study within one year of the feasibility of a new facility. Such a study was requested in the NRC's February 20, 1980 letter to DOE Under Secretary John Deutch and was committed to in Deutch's March 13 reply. No such study has been conducted.

In retrospect, I believe that Commissioner Gilinsky's suggestion that surveillance of the facility be vested in DOE (11 NRC 807–8) may well have been correct. The useful purpose that I saw in retaining juriadiction was the potential to compel significant improvement, for this is dangerous material to lose track of. However, I doubt the usefulness of a regulatory regimen that functions as tolerantly as this one does now.

[7] See the views of Commissioner Ahearne at 11 NRC 799, 812–816. His suggested "stipulation of as many facts as possible" (at 816) is a desirable step, but one that would be considerably aided by the certainty of an adjudicatory hearing for issues of material fact on which no stipulation had been reached.

[8] The Commission has dropped the ill-considered language in the original rule implying that protection of classified information was at issue here, but the Department of Energy has sought to keep up the pretense in its comments. The fact is that our present rules give ample authority to assure that no classified information falls into unauthorized hands as a result of any type of NRC proceeding. Classified information will be fully protected in any type of proceeding whether or not this rule is adopted.

[9] The following exchanges took place at the affirmation session on June 26, 1980.

Concerning the immediately effective rule to exempt from Part 2 adjudications relating to military and foreign functions: "Chairman Ahearne: Mr. Bickwit, may I ask you a legal judgment since I read at least one of the dissents. Is this a legal action you're [sic] taking?

"Mr. Bickwit: Yes, I believe they are."

Affirmation session, transcript at 6 (June 26, 1980).

Concerning the Commission order and notice of hearing: "Chairman Ahearne: I would like to ask the General Counsel the same question. Is this a legal action?

"Mr. Bickwit: I do believe it is. Yes."

Affirmation session, transcript at 8 (June 26, 1980).

[10] In reaching its initial decision concerning Erwin, the Commission specifically noted "the essential role of the NFS-Erwin facility in supplying material for the Naval nuclear propulsion program and thus for the common defense and security." Memorandum from S. J. Chilk, Secretary to L. V. Gossick, EDO (January 21, 1980) (memorandum documenting Commission decision). A more precise description of the connection is difficult because it would involve classified material.

[11] *Nuclear Fuel Service, Inc.* (Erwin, Tennessee), CLI–80–27, 11 NRC 799 (1980). Two fundamental issues raised by this licensing action are (1) the value of NRC review of DOE activities, and (2) the propriety of trading material control and accounting measures for physical security given non-proliferation concerns about the international precedent. These are basically policy issues which only the Commission can decide and which must be decided in light of the defense policy considerations.

Engineering, Office of Nuclear Reactor Regulation, Washington, D.C. 20555, Telephone: (301) 492–4891.

SUPPLEMENTARY INFORMATION:

A. Background

In connection with the prelicensing antitrust review of production and utilization facility applicants (primarily nuclear power reactor owners and operators), Section 105c(2) of the Atomic Energy Act of 1954, as amended, 42 U.S.C. 2135c(2), requires the NRC to forward to the Attorney General, for his antitrust advice, a copy of the operating license ("OL") application if:

> * * * the Commission determines such review is advisable on the ground that significant changes in the licensee's activities or proposed activities have occurred subsequent to the previous review by the Attorney General and the Commission under this subsection in connection with the construction permit for the facility.

On September 12, 1979, the Nuclear Regulatory Commission delegated its authority to make the "significant changes" determination under Section 105c(2) to the Director of Nuclear Reactor Regulation or the Director of Nuclear Material Safety and Safeguards, as appropriate depending on the particular kind of production or utilization facility involved. In connection with that delegation, the Commission approved procedures to be used until such time as regulations implementing those procedures were adopted. Although never formally published, these procedures were and are available as attachments to SECY–79–353 (May 24, 1979) and SECY–81–43 (January 19, 1981) in the Commission's Public Document Room, at 1717 H Street, NW., Washington, D.C. On March 26, 1981, the Commission published for comment in the **Federal Register** a proposed rule to implement the approved procedures (46 FR 18747).

B. Comments

Three comment letters were received from two electric utilities, Carolina Power & Light Company (CP&L) and Arizona Public Service Company (APS), and from one law firm, LeBoeuf, Lamb, Leiby & MacRae (LeBoeuf Lamb), that represents several electric utilities. Copies of these comments and an NRC staff analysis of them are available in the Commission's Public Document Room.

1. *Carolina Power & Light Company ("CP&L").* Under the procedures as originally proposed, the NRC would publish a notice in the **Federal Register** of receipt of antitrust information submitted in connection with an OL application. The notice would direct that comments on the antitrust aspects of the application should be submitted within 60 days to the NRC for presentation to the Attorney General. The proposed procedures envisage receipt of comments and information back from the Attorney General prior to making a "significant changes" determination. CP&L suggested, first, that there should be a fixed time limit of 20 days after receipt of the Attorney General's comments in which the appropriate Director would be required to make the "significant changes" determination.

The Commission has not adopted CP&L's modification because it would establish a single, rigid time schedule without any flexibility. In some situations, full and fair consideration of potentially complex antitrust allegations and factual material may require longer then 20 days. CP&L's suggestion fails to make any accommodation for such case-by-case variations and is, therefore, undesirable.

The proposed rule permitted members of the public a 60-day period in which to submit their comments in response to the **Federal Register** notice of receipt of OL antitrust information, and also permitted another 60-day period in which to request reevaluation of a Director's finding of no significant changes. CP&L asserted that the two proposed 60-day periods should be shortened to be consistent with the Proposed Rule for Expediting the NRC Hearing Process (46 FR 17216, March 18, 1981). The final rule has been changed to provide a 30-day period for the submittal of comments in response to the notice of receipt of OL antitrust information submitted pursuant to Regulatory Guide 9.3. The Commission believes that 30 days is sufficient time to afford to the public a meaningful opportunity to submit relevant antitrust information to the NRC and to the Attorney General without undermining efforts to expedite the processing of OL applications. In addition, in response to CP&L's comment about the excessive length of time for submitting requests for reevaluation of a significant changes determination, this period has been decreased from 60 days to 30 days in the final rule.

2. *LeBoeuf, Lamb, Leiby & McRae ("LeBoeuf Lamb").* LeBoeuf Lamb pointed out that the phrase, "the antitrust portion of an application for a facility operating license," in the proposed revision to 10 CFR 2.101(c) is incorrect because antitrust information submitted at the OL stage is not a formal part of the OL application. To better indicate the correct relationship between the antitrust information submitted at the OL stage and the OL application itself, the Commission has, in the final rule, replaced that phrase with the phrase "information responsive to Regulatory Guide 9.3 submitted in connection with an application for a facility operating license."

LeBoeuf Lamb, as well as Arizona Public Service Company, also maintained that NRC consultation with the Attorney General prior to making the significant changes determination is contrary to Section 105c(2) of the Act and should be eliminated. Section 105c(2) addresses the Commission's obligation to make the significant changes determination, upon which a full-scale antitrust review and formal rendering of advice by the Attorney General necessarily depends. It is true that Section 105c(2) itself is silent on whether the Commission can or should consult with the Attorney General prior to making the significant changes determination.

The legislative history of Section 105c(2), however, is not silent on this point and explicitly states Congress' intention that this pre-determination consultation should occur. The Joint Committee on Atomic Energy, in connection with the 1970 amendments that added the Section 105c provisions for prelicensing antitrust review, stated that, as to OL applications: "The committee expects that the Commission will consult with the Attorney General in regard to its determination respecting significant changes." H. Rep. No. 91–1470, 91st Cong., 2d Sess., *reprinted in* 3 U.S. Code, Cong. and Adm. News, 91st Cong., 2d Sess., 4981, 5009 (1970). In light of this express Congressional direction and in light of the obvious benefits gained from the sharing of information and ideas with the Attorney General, the final rule retains the pre-determination consultation provisions.

LeBoeuf Lamb also objected to two "public comment" periods provided under § 2.101 in the proposed rule, ostensibly referring to the comment period provided in the Federal Register notice of receipt of OL antitrust information and to the period in which reevaluation of a no significant changes finding can be requested. LeBoeuf Lamb asserted that the second was not likely to be useful. The final rule does not include LeBoeuf Lamb's suggestion to eliminate one of the two so-called "comment" periods. The first notice announces receipt of Regulatory Guide 9.3 antitrust information submitted in connection with the OL application. At this time, the antitrust inquiry by the Commission and the Attorney General is not specifically focused on any particular information, and public comments may provide a useful background for the NRC and Attorney General review. The second time period in which members of the public can request reevaluation of a no significant changes finding is initiated by publication of a Federal Register notice. That notice contains the Director's initial finding and underlying rationale, and also indicates the availability of any other staff analysis, thus permitting the public to base any request for reevaluation upon specific facts or conclusions directly related to the initial significant changes finding. This second stage for public involvement is a more focused one, which is expected to bring to light any relevant information that might have otherwise not been available to the Director in making the finding. Taken together, these two periods for public input, with their differing emphases, should provide sufficient and current information, supplemented where necessary by independent NRC follow-up activities, upon which a fair and reasoned final significant changes determination can ultimately be made.

3. *Arizona Public Service Company ("APS").* APS also opposed providing the public with any expanded opportunity to submit pertinent antitrust information and comments to the NRC in connection with making the significant changes determination. APS raised concerns about the receipt of comments leading to possible delay in making the significant changes determination, as well as about an increased potential for formal review by the Attorney General and for NRC antitrust hearings, which could cause more licensing delays.

The Commission believes that the reduced 30-day period for submitting public comments, as well as the comments themselves, will not lead to unwarranted or significant delays in the NRC licensing process. The 30-day period accommodates the need for expedition in licensing with the idea that public comments will contribute to a more informed and less speculative significant changes determinatioin. To fulfill its statutory obligations under Section 105c, the NRC must have the most current and complete information possible. It would be short-sighted to eliminate one potentially valuable mechanism by which to obtain such information—comments from the public itself, including other utilities in and around the applicant utility.[1]

C. Other Minor Changes in Final Rule

Several minor editorial changes have been made in the final rule to eliminate certain ambiguities, to correct inaccurate terminology, and to ensure consistency in the Commission's regulations. Among these are the following principal changes:

(1) Sections 1.42, 1.61(e), and 2.101(c)(3): changes have been made to indicate the most current NRC internal organizational structure and division of responsibilities;

(2) Section 2.101(c): clarification that § 2.101(c) applies only to construction permit applications, as reflective of current staff practice;

(3) Section 2.101(e) and Appendix A: changes have been made concerning the timing and nature of the notice of receipt of construction permit application antitrust information and the Regulatory Guide 9.3 OL antitrust information. The changes also include clarification that public comments submitted will be considered by the NRC and will also be forwarded to the Attorney General; and

(4) Section 2.104(d)(3): clarification of the NRC procedures concerned with notices of hearing, to make it clear that the invitation for the public to submit comments on antitrust matters in the notice of receipt of the OL antitrust information has no effect whatsoever on whether an OL hearing will or should be held on health, safety, environmental, or other matters under the provisions of § 2.104(d). In that regard, prelicensing antitrust reviews and hearings are governed by the provisions of section 105c of the Atomic Energy Act of 1954, as amended, *Houston Lighting and Power Co.* (South Texas Project, Unit Nos. 1 and 2), CLI-77-13, 5 NRC 1303 (1977), and are subject to separate licensing proceedings from those concerned with health, safety, and environmental matters, *Public Service Co. of Indiana* (Marble Hill Nuclear Generating Station, Units 1 and 2), ALAB-316, 3 NRC 167 (1976).

Paperwork Reduction Act Statement

Pursuant to the provisions of the Paperwork Reduction Act of 1980 (Pub. L. 96-511), the NRC has made a determination that these amendments do not impose new recordkeeping, information collection, or reporting requirements.

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the NRC hereby certifies that the promulgation of this rule will not have a significant economic impact on a substantial number of small entities. The rule implements current NRC internal procedures related to the licensing of production and utilization facilities under Section 103 of the Atomic Energy Act of 1954, as amended, 42 U.S.C. 2133. In addition, the companies (primarily electric utilities) owning and operating these facilities are dominant in their service areas and/or do not fall within the definition of a small business found in Section 3 of the Small Business Act, 15 U.S.C. 632, or within the Small Business Size Standards set forth in 13 CFR Part 121. Accordingly, there is no significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act of 1980.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and Section 553 of Title 5 of the United States Code, notice is hereby given that the following amendments to Title 10, Chapter 1, Parts 1 and 2, Code of Federal Regulations, are published as a document subject to codification.

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47 FR 9987
Published 3/9/82
Effective 3/9/82
Correction 47 FR 16005

10 CFR Part 2

General Statement of Policy and Procedure for Enforcement Actions

AGENCY: Nuclear Regulatory Commission.

ACTION: Revised general statement of policy.

SUMMARY: The NRC is revising its enforcement policy based on: (1) experience gained in the implementation of the proposed general guidance to the staff since that guidance was published in October 1980; and (2) comments received during and following public meetings on the policy. The policy statement is intended to inform licensees and the public of the bases for taking various enforcement actions. The policy, which provides guidance, is being codified as Appendix C to Part 2 of Title 10 of the Code of Federal Regulations.

EFFECTIVE DATE: March 9, 1982.

FOR FURTHER INFORMATION CONTACT: James Lieberman, Acting Director, Enforcement Staff, Office of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555 (301-492-4909).

SUPPLEMENTARY INFORMATION: The Nuclear Regulatory Commission is revising its enforcement policy to respond to comments provided on an earlier version published in October

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[1] APS asserted the NRC can and should issue operating licenses irrespective of whether the significant changes determination or the completion of an antitrust review have occurred, citing Kansas Gas and Electric Co. (Wolf Creek Generating Station, Unit No. 1), ALAB-279, 1 NRC 559 (1975), and H. Rep. No. 91-1470, 91st Cong., 2d Sess. 31 (1970). These authorities and the issue raised by APS do not address the subject of this rule—the procedures for making a significant changes determination—nor do they provide, without any explanation by APS, an acceptable legal basis for the Commission to agree or disagree with the assertion made.

1980 and to reflect experience gained in use of the interim policy. The revised policy describes the general bases on which various enforcement sanctions are to be used as part of the NRC's regulatory program. The statement of general policy set forth below (as Appendix C to Part 2) is intended to serve as Commission guidance, rather than as rigid requirements.

Background

The criteria used by the Commission's staff to determine categories of noncompliance and enforcement actions arising therefrom (referred to hereafter as "Criteria") were first published on October 17, 1972 (37 FR 21962). These Criteria were subsequently modified on January 3, 1975 (40 FR 820) and on December 3, 1979 (44 FR 77135). In late 1979, the Commission directed the staff to prepare a comprehensive statement of enforcement policy. This staff effort received added urgency with the enactment of Pub. L. 96–295 (signed June 30, 1980), that, among other things, amended Section 234 of the Atomic Energy Act to raise the maximum civil penalty the NRC can impose from $5,000 to $100,000 per violation and eliminated the provision limiting the total civil penalties for any 30-day period to $25,000.

On September 4, 1980, the Commission approved a proposed general statement of policy on enforcement, and directed the staff: (1) To implement the proposed policy as interim guidance; (2) to publish the proposed policy for public comment; and (3) to conduct a series of public meetings to obtain and consider public comments on the proposed policy.

The proposed policy was published in the **Federal Register** on October 7, 1980 (45 FR 66754). A series of five public meetings was announced on October 17, 1980 (45 FR 69077) and copies of both those **Federal Register** items were mailed to all NRC licensees and to identified public interest and intervenor groups, soliciting their participation in the meetings.

Results of Meetings

Public meetings were held in early December 1980, as scheduled, in Philadelphia, PA, Atlanta, GA, Chicago, IL, Dallas, TX, and Oakland, CA. Attendance at the meetings varied from about 35 (at the Dallas and Oakland meetings) to a little over 100 (at the Philadelphia and Chicago meetings). All meetings were transcribed, and transcripts are available in the NRC's Public Document Room at 1717 H Street NW, Washington, DC 20555.

In addition to comments received at the public meetings, written comments were submitted by 162 individuals and/or groups. All comments were carefully considered by the staff in its revision of the policy, and where appropriate, the policy was revised to accommodate them. The nature of both verbal and written comments ranged from highly critical to enthusiastically supportive. In general, however, the thrust of the comments was unfavorable, with criticism most often directed at: (1) The generally perceived adversarial tone of the policy; (2) the lack of more explicit consideration of extenuating conditions as they might apply to individual cases, thus arguing for more flexibility for the staff to apply judgment and discretion in enforcement decisions; (3) inadequate recognition of effective licensee audit programs designed to identify and correct problems internally; (4) inconsistency among the severity levels assigned to violations in the various activity areas; (5) lack of clarity in the examples of violations in the supplements; and (6) inadequate distinctions between severity levels, particularly for the less serious violations.

Representative concerns (as paraphrased by the staff) frequently expressed in both the public meetings and the writtern comments, and the NRC staff responses to them are set forth below. In addition, a compilation of all written comments, and staff responses to them, has been prepared and will be made available soon in the NRC Public Document Room and through the National Technical Information Service (NTIS), Springfield, VA, as an NRC report (NUREG–0736). Many of the oral presentations at the public meetings were reiterated in the written comments, and the general thrust of all the oral presentations closely paralled the written comments.

Comment: The Commission should be involved in any decisions deviating from the stated enforcement policy, whether that deviation results in a greater or lesser civil penalty.

Response: The Commission is notified before proposing each civil penalty. However, requiring the Commission to rule on each deviation would create an undue burden on the Commission. Currently the policy calls for Commission review when:

a. The proposed action may in itself involve public health and safety risks;

b. The Commission feels it is desirable;

c. The Director feels it is appropriate; or

d. A civil penalty for a single violation exceeds 3.75 times the base amount of a severity level I violation.

Comment: In implementing this policy NRC should follow the requirements of the Regulatory Flexibility Act of 1980.

Response: This policy is not subject to the Regulatory Flexibility Act.

Comment: The size of a fine should be based on hazard, not the ability to pay.

Response: The legislative history of section 234 indicates that ability to pay is a factor to be considered in assessing civil penalties. The structure of Table 1 does reflect generally the nature of hazard involved in licensed activities. A civil penalty is not designed to put a licensee out of business. Where it is appropriate to terminate licensed activities, an order, rather than a civil penalty, is used.

Comment: It should not be NRC policy to fine individual operators licensed under 10 CFR Part 55.

Response: Enforcement actions for licensed opeators will be determined on a case-by-case basis, as specified in Section IV.A. of the Policy Statement.

Comment: Inadvertent errors must be accepted as a distinct possibility and severe penalties should be reserved for willful violations only.

Response: NRC expects, and has required, a high standard of licensee compliance; this policy is designed to ensure that this high standard is maintained. Clearly, willful violations should be treated more harshly. A willful violation may be a criminal violation under the Atomic Energy Act and may be referred to the Department of Justice for appropriate action.

Comment: Insufficient time was allowed to prepare for pubic meetings.

Response: The meetings were announced on October 17, 1980 and were held in early December, 1980; a period of at least six weeks to prepare for the meetings.

Comment: Insufficient time has been allowed for written comments.

Response: All comments received before June 1981 were considered in the policy modification, although the formal closing date for receipt of comments was December 31, 1980, which provided almost three months from date of publication in the Federal Register for preparation of written comments.

Comment: The policy should be withdrawn until an assessment can be made as to the necessity of new regulations.

Response: This policy does not add any new requirements. Rather, it announces how the NRC will enforce existing requirements.

Comment: The Office Directors should have more discretion.

Response: The Office Directors have broad discretion. The policy allows for discretion while ensuring that sufficient guidance is present for its even application.

Comment: Any civil penalties imposed on nonprofit hospitals or other nonprofit institutions would have to be paid by increasing charges to the public.

Response: Table 1 has been modified to address this concern. The Commission does not desire to increase consumer costs. Nevertheless, the Commission believes that civil penalties provide both profit-making and nonprofit institutions incentives for safety through compliance with its requirements.

Comment: What criteria were used to place particular violations in their corresponding severity levels?

Response: The actual or potential impact on the health and safety of the public is the fundamental basis for this determination within each activity area. It is inappropriate, however, to compare severity levels between activity areas.

Comment: Are the supplements for guidance only or are they mandatory?

Response: The supplements are for guidance, as is the entire policy statement.

Comment: The aggressive use of monetary civil penalties will not ensure compliance with NRC regulations.

Response: While not ensuring compliance, civil penalties are strong incentives to comply. Enforcement actions are almost exclusively retrospective in nature, of course, and thus address past noncompliance rather than guaranteeing compliance. Nevertheless, the deterrent effect of enforcement, including civil penalties, is considered to be substantial. In addition, it is Commission policy that noncompliance should be more expensive than compliance.

Comment: The language used in the introduction and purpose invites a counterproductive adversarial relationship.

Response: The language in the introduction and purpose has been changed to address this concern.

Comment: The requirement to submit responses to Notices of Violation under oath or affirmation is unnecessary and contributes to an adversarial tone. It should not be required for all responses.

Response: The across-the-board requirement has been eliminated for other than escalated enforcement actions, but the decision to require such sworn responses remains an NRC option under Section 182 of the Atomic Energy Act. The Commission continues to expect accurate, complete and timely information from licensees. The elimination of the oath requirement will not prevent the Commission from taking enforcement action for responses that do not meet that expectation.

Comment: Civil penalties should not be imposed for the same violation which is the basis for a license revocation or suspension.

Response: The Atomic Energy Act expressly provides for civil penalties to be assessed for any violation which would warrant license revocation. The decision as to whether both revocation (or suspension) and civil penalties should be applied for the same violation is made on a case-by-case basis.

Comment: The matching of severity levels to civil penalties may make it easier for the NRC to determine a civil penalty and/or any other sanction, but it takes away from the licensee any chance of proving the existence of mitigating circumstances.

Response: Prior to imposing civil penalties, licensees are given the opportunity to raise any mitigating circumstances unique to the case. These circumstances are taken into consideration when the decision is made whether or not to order the imposition of civil penalties. Mitigation or remission of civil penalties based on such licensee responses is not uncommon when compelling arguments are presented.

Comment: Provisions for escalated action set forth in Table 2 are not appropriate.

Response: Table 2 is advisory, not mandatory.

Comment: Severity levels need to be revised to more clearly reflect health and safety concerns.

Response: The number of severity levels has been reduced to five, with additional guidance in expanded supplements.

Comment: Immediate Action Letters should be called Confirmatory Action Letters.

Response: Adopted.

Comment: Is the Enforcement Policy a General Statement of Policy or a regulation?

Response: An underlying basis of this policy that is reflected throughout it is that the determination of the appropriate sanction requires the exercise of discretion such that each enforcement action is tailored to the particular factual situation. In view of the discretion provided, the enforcement policy is being adopted as a statement of general policy rather than as a regulation, notwithstanding that the statement has been promulgated with notice and comment procedures. A general statement of policy will permit the Commission maximum flexibility in revising the policy statement and it is expected that the statement, especially the supplements, will be revised as necessary to reflect changes in policy and direction of the Commission.

In drafting the statement it was expected that the specific enforcement criteria should provide adequate guidance and be applied in the majority of circumstances requiring enforcement actions. The policy, as indicated above, does provide discretion to take appropriate action if, after considering the policy statement, the Director determines that application of the criteria is inappropriate. For example, there may be cases where more than a 25% increase in civil penalty is appropriate based on prior enforcement history.

Principal Changes

The fundamental basis of the revised policy remains the same as that articulated in the interim policy. That is, violations are categorized by severity level in accordance with guidance incorporated in the policy statement. Based on that severity level, the enforcement sanction to be applied is then determined. Depending on the nature of the licensed activity involved, the size of any base civil penalty that may be called for is then determined and adjusted upward or downward based on the circumstances of the specific case.

In spite of these basic similarities, substantial changes have been made in how the steps are accomplished and in clarifying the language used to present the policy. The most significant of these changes include: (1) Reduction in the number of severity levels from six to five; (2) provision that severity level III violations be considered for civil penalties, but not necessarily imposed in every instance of a severity level III violation*; (3) elimination of civil penalties for violations identified, corrected and reported by licensees under certain conditions; (4) elimination of specific criteria for enforcement actions against licensed operators; (5) modification of the tone of presentation to avoid an unnecessarily adversarial character; (6) changes in the base civil penalty values to better differentiate among different types of licensees; (7) clarification of a number of passages and of several terms used in the policy; (8) addition of a new supplement containing guidance on miscellaneous matters, including violations involving material false statements, willful violations and reporting failures; and (9) combination of the supplements applicable to fuel cycle operation and materials activities into one supplement.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and Section 552 of Title 5 of the United States Code, the following statement of policy is published as Appendix C to 10 CFR Part 2 as a document subject to codification to be effective March 9, 1982.

*Correction 47 FR 16005

47 FR 13750
Published 3/31/82
Effective - See Text

10 CFR Parts 2 and 50

Elimination of Review of Financial Qualifications of Electric Utilities in Licensing Hearings For Nuclear Power Plants

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations to eliminate entirely requirements for financial qualifications review and findings for electric utilities that are applying for construction permits or operating licenses for production or utilization facilities. The Commission is also amending its regulations to require power reactor licensees to obtain on-site property damage insurance, or an equivalent amount of protection (e.g., Letter of credit, bond, or self insurance), from the time that the Commission first issues an operating license for the nuclear reactor.

EFFECTIVE DATE: For amendments eliminating financial qualifications review (§ 2.104, Sections VI and VIII of Appendix A to Part 2, §§ 2.4, 50.2, Appendix C to Part 50, Appendix M, paragraph 4.(b) to Part 50, § 50.33(f), and § 50.40), Mar. 31, 1982. For amendments establishing on-site property damage insurance requirement (§§ 50.54(w) and 50.57), June 29 1982. In accordance with the Paperwork Reduction Act of 1980, (44 U.S.C. 3507), the reporting provision that is included in paragraph (w)(5) of § 50.54 has been submitted for approval to the Office of Management and Budget (OMB). It is not effective until OMB approval has been obtained.

FOR FURTHER INFORMATION CONTACT: Jim C. Petersen, Office of State Programs, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (telephone 301–492–9883).

SUPPLEMENTARY INFORMATION:

I. Background

On August 18, 1981, the Commission published a notice of proposed rulemaking in the **Federal Register** (46 FR 41786) concerning requirements for financial qualifications review and findings for electric utilities that are applying for permits or licenses for production or utilization facilities. As proposed, the rule would have:

(1) Eliminated entirely financial qualifications review requirements for construction permit applicants; and

(2)(i) Also eliminated entirely these requirements for operating license applicants; or

(ii) Retained these requirements for operating license applicants to the extent they require submission of information concerning the costs of permanently shutting down the facility and maintaining it in a safe condition (i.e., decommissioning costs).

Concurrently, the Commission proposed amending its regulations to require, on an interim basis, power reactor licensees to "maintain the maximum amount of commercially available on-site property damage insurance, or an equivalent amount of protection (e.g., letter of credit, bond, or self insurance), from the time that the Commission first permits ownership, possession, and storage of special nuclear material at the site of the nuclear reactor."

In the **Federal Register** notice, the Commission based its proposal for this rulemaking, in part, upon the statutory basis in the Atomic Energy Act of 1954, as amended ("AEA") for the financial qualifications regulations and its discussion in *Public Service Company of New Hampshire, et. al.* (Seabrook Station, Units 1 and 2), CLI–78–1, 7 NRC 1 (1978) *("Seabrook")*. In that decision and the proposed rulemaking, the Commission affirmed its belief that the existing financial qualifications review has done little to identify substantial health and safety concerns at nuclear power plants. However, because the Commission believed that there are matters important to safety which may be affected by financial considerations, it requested comments regarding the type of NRC financial review that would focus effectively on considerations that might adversely affect safety.

II. Public Comments on the Proposed Rule

Over 160 comments were received on the proposed rulemaking and have been categorized as follows:

Private citizens—98 comments received
Public interest groups—30 comments received
Insurance groups—2 comments received
Legal counsel—8 comments received
Governmental organizations and individuals—10 comments received
Utilities and utility groups—16 comments received
Architect-engineers and contractors—2 comments received

All private citizen comments and all but two public interest group comments oppose reducing or eliminating the Commission's financial qualification review requirements. However, they generally support imposing immediate decommissioning financing requirements and also requiring licensees to demonstrate their ability to clean up after an accident. By contrast, utilities, utility groups, and utility contractors support completely eliminating the Commission's financial qualifications requirements, including decommissioning. Further, utilities and their representatives generally oppose requiring mandatory property damage insurance. Comments from legal counsel generally reflected the interests and views of their utility, insurance, or public interest clients. Governmental organizations and individuals reflected a spectrum of views, although most were against eliminating the financial qualifications review. Some states and municipalities identified potential legal conflicts between certain provisions of the proposed rulemaking and state law. A summary of the comments is presented below. Those who are interested may obtain copies of specific comments from the Public Document Room or the NRC Secretary under designation PR–50 (46 FR 41786), by writing to: Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

A. *Reducing or eliminating the Commission's financial qualifications review.* Those arguing against reducing or eliminating the Commission's financial qualifications review make four major points. First, they discount NRC's presumption that public utilities can meet the financial demands of constructing and operating nuclear plants. Citing Seabrook, WPPSS, TMI, South Texas and other examples, commenters maintain that utilities often have experienced and will continue to experience difficulty in raising funds to cover capital, operating, and maintenance costs (particularly in periods of high interest rates and overcapacity), whether or not such costs can be recovered in the rate base through Construction Work in Progress (CWIP) or otherwise recovered in rates. Second, these commenters maintain that the inability to recover all costs provides an incentive for utilities to skimp on important safety components and quality assurance standards. Some commenters cite the discussion of financial disincentives in the *Rogovin Report (Three Mile Island: A Report to the Commission and the Public,* Mitchell Rogovin, Director, January 1980) to support their views. Another commenter suggests that utilities will be tempted to lower wages which would lead to higher turnover and, thus, to employment of inadequately trained personnel. Third, commenters maintain that NRC inspection efforts and capabilities are inadequate to provide sufficient assurance of safety. Even if violations are found, some commenters argue that NRC enforcement efforts are inadequate. Fourth, the commenters assert that the financial qualifications review function is statutorily required by 42 U.S.C. 2232(a), (c) and (d).

Further, many of those arguing against eliminating the financial qualifications review recommend that the Commission should at least retain that portion of the review pertaining to decommissioning. They state that the ongoing decommissioning rulemaking is no substitute for an immediate general requirement to demonstrate financial capability to decommission a nuclear production on utilization facility safely and expeditiously. Many expressed the view that the generic decommissioning study would not be completed in a reasonable time.

By contrast, those favoring the Commission's proposed reduction or elimination of the financial qualifications review function generally support the Commission's reasoning that such a review has done little to identify substantive health and safety problems at nuclear power plants and that the Commission's inspection and enforcement activities provide more effective protection of public health and safety. Most utilities and their associates support complete elimination of the financial qualifications review, including provisions pertaining to decommissioning. These commenters maintain that, if any regulations relating to the financing of decommissioning are adopted, they should await completion of the Commission's generic rulemaking on decommissioning.

The Commission has received no comments to persuade it to change significantly its reasoning on the proposed financial qualifications rule. As indicated above, many of those opposing the proposed rule change have concluded that experience with Seabrook, WPPSS and other plants demonstrates the close connection between financial qualifications and public health and safety. The Commission disagrees. As to the first point raised by commenters opposing elimination of the financial qualifications review, the Commission does not find any reason to consider, in a vacuum, the general ability of utilities to finance the construction of new generation facilities. Only when joined with the issue of adequate protection of the public health and safety does this issue become pertinent. As to this, the commenters' second point, the Commission in its *Seabrook* decision indicated its support for the substance of the proposed rule—elimination of the financial qualifications review because of the lack of any demonstrable link between public health and safety concerns and a utility's ability to make the requisite financial showing.

The actual financial situation analyzed in that case has not changed. There is no evidence that the safety of the public has been adversely affected by Public Service Company of New Hampshire's (PSCNH) difficulties in obtaining financing. It is true that to raise capital, PSCNH has sold part of its ownership in the Seabrook plant, but such action does not have any demonstrable link to any safety problems. Similarly, citing WPPSS' experience is not convincing, because WPPSS' response (and that of most other utilities encountering financial difficulties) has been to postpone or cancel their plants, actions clearly not inimical to public health and safety under the Atomic Energy Act.

As to the third point raised in opposition to the proposed rule, in the absence of facts to the contrary, the Commission cannot accept unsupported statements that, as a general matter its inspection and enforcement efforts are inadequate. The examples that commenters cite (e.g., South Texas) appear to substantiate, rather than undercut, the Commission's view that any violations of safety regulations are being found and corrected and that, in any event, such violations cannot be shown to arise from a licensee's alleged lack of financial qualifications.

With respect to the final assertion that the financial qualifications review function is statutorily mandated, Section 182a of the AEA, 42 U.S.C. 2232(a), clearly indicates that such function is within the Commission's discretionary authority, but is not mandated. As noted in the proposed rule, this interpretation of Section 182a has been approved by the United States Court of Appeals for the First Circuit in *New England Coalition on Nuclear Pollution v. NRC*, 582 F.2d 87, 93 (1978), affirming the NRC's *Seabrook* decision.

On balance, after careful consideration of the comments submitted and of the factors discussed in the notice of proposed rulemaking, the Commission has elected to promulgate the first of the two alternatives outlined in the proposed rule, i.e., eliminate the financial qualifications review of electric utilities entirely at the CP and OL stages, including elimination of any consideration of decommissioning funding. This is not meant to discount the importance of decommissioning funding to public health and safety, but rather recognizes that any action on decommissioning is more appropriate in the context of the generic rulemaking now being conducted. Until that time, the Commission has concluded that it is premature to include any final decision on decommissioning in this final rule on financial qualifications. Because the generic decommissioning rule is scheduled to be published in 1982 and since all licensees will be required to meet any financial requirements imposed as a result of that rulemaking, there should be little practical effect in temporarily eliminating consideration of decommissioning funding from licensing activities. Moreover, if decommissioning financing issues were continued to be allowed in current licensing proceedings, two undesirable effects may result. First, there would be an increased chance that findings in such cases might contradict evolving Commission policy in this area. Second, one positive gain from the final rule would be countered, in that there could be expected to be little, if any, reduction in the contentions before the licensing boards on financial qualifications issues, thereby not significantly reducing the time and effort devoted to those issues.

B. *Mandatory property insurance for decontamination.* Comments are similarly divided on the issue of requiring on-site property insurance to cover decontamination expenses resulting from an accident. Those who support keeping the financial qualifications review generally support requiring a utility to demonstrate proof of its ability to clean up after an accident. The Commission interprets these comments as supporting mandatory property insurance, insofar as it covers accident cleanup costs. The other commenters favoring elimination of the financial qualifications rule generally either (1) oppose mandatory coverage outright because of recent self-initiated moves by the utility industry to obtain insurance or, (2) favor substantial modification of the rule to clarify several of its provisions.

The first group of commenters do not generally state their reasons for favoring mandatory insurance except for an undefined and non-quantifiable general benefit in protecting public health and safety. Some indicated that the amount of insurance currently available is not sufficient to cover accidents such as TMI-2. However, because of recently announced increases in the amount of coverage available and the continuing evolution in the insurance markets, this concern may not be as great as might otherwise be the case.

As indicated above, the second group of commenters—primarily utilities and their representatives—object more to the wording of certain provisions of the proposed on-site property damage insurance rule than to the requirement itself. Several commenters recognize that the practical effect of requiring mandatory insurance has been reduced, particularly since the TMI-2 accident, because most utilities will buy whatever amount of coverage is offered, within reasonable limits, as a matter of good business judgment. Other commenters indicate that the Commission's estimates of annual premiums required for a typical reactor may have been understated. Estimated premiums for coverage currently available (i.e., $375 or $450 million) are $3 million per year for a typical two-unit site.

In light of these comments and for the reasons stated in the proposed rule, the Commission has decided to retain the requirement in the final rule that electric utilities must have on-site property damage insurance, but several modifications have been made pursuant to the comments received. The following changes have been incorporated into the text of the final rule on property insurance:

1. The definition of "maximum available amount" has been clarified. This term could have been interpreted to mean that utilities would be required to switch their insurance coverage to the carrier offering the greatest amount at any particular time. Another interpretation could be that utilities would be required to obtain coverage from the two major insurers or any other insurer that decides to enter this market. Finally, the "maximum available" could have included any increment no matter how highly priced or how restrictive the terms and conditions. The Commission's intent is neither to disrupt the insurance markets by forcing utilities to switch their insurance carriers unnecessarily nor to require utilities to obtain insurance under unreasonable terms and conditions. The rule has been changed to clarify the Commission's intent, specifically in § 50.54(w).

2. Some commenters maintained that the proposed rule should apply only to insurance covering decontamination of a facility suffering an accident and not to "all risk" property damage insurance. Because decontamination insurance is the Commission's only concern from the point of view of protecting public health and safety, coverage to replace the existing facility on an "all risk" basis is beyond the scope of the Commission's authority. By the same reasoning, the Commission disagrees with the position taken by some commenters that it is unfair to many owners of smaller power reactors to require insurance greatly exceeding the cost of replacing the facility. A TMI-2 type accident could well require coverage approaching $1 billion, no matter what the original value or size of the facility. The Commission expects that the required insurance will cover reasonable decontamination and cleanup costs associated with the property damage resulting from an accident at the licensed facility. Until completion of studies evaluating the cost of cleaning up accidents of varying severity, it is prudent to require for all power reactors a reasonable amount of insurance for decontamination expense.

3. Several persons commented that reactor licensees should not be required to maintain on-site property damage insurance until the operating license has been received. With fuel merely stored at a reactor, the chance of an accident requiring extensive decontamination is extremely remote. The Commission agrees and has changed the rule accordingly, so that such insurance need be in force only when the utility is licensed to operate the reactor.

4. Several Texas utilities commented that the Texas constitution (and, apparently, the Louisiana and Idaho constitutions) prohibits certain municipal utilities from purchasing insurance either offered by mutual insurance companies or involving retroactive assessments. The Commission has revised the rule to address these concerns.

5. One commenter discussed the need to clarify the amount of time required of the licensee to obtain not only initial insurance but also subsequent increases offered. Another suggested that many regulated utilties may have difficulty in obtaining approval to purchase insurance within 90 days. The Commission has revised the rule to reflect its view that 90 days is a reasonable time in which to take reasonable steps to obtain both initial and any additional on-site property damage insurance.

6. The phrase "commercially available" insurance could have been construed to exclude insurers such as NML and NEIL. The Commission recognizes this possible but erroneous interpretation and has changed the wording of the rule accordingly.

III. Other Considerations

A. *Requirement for Additional Information.* As indicated in the proposed rule, the Commission does not intend to waive or relinquish its residual authority to require such additional information in individual cases as may be necessary for the Commission to determine whether an application should be granted or denied or whether a license should be modified or revoked. See, for example, the fourth sentence of Section 182a of the AEA. Similarly, no change in the present powers of the Commission with regard to the financial qualifications review of non-utility applicants for Part 50 licenses will be made. In addition, an exception to or waiver from the rule would be possible to require the submission of financial information from a particular electric utility applicant if special circumstances are shown pursuant to 10 CFR 2.758 in an individual licensing hearing.

B. *Practical Impacts.* Also as indicated above and in the proposed rule, the Commission continues to expect that the final rule will, in normal circumstances, reduce the time and effort which applicants, licensees, the NRC staff and NRC adjudicatory boards devote to reviewing the applicant's or licensee's financial qualifications. The rule will eliminate staff review in cases where the applicant is an electric utility, presumed to be able to finance activities to be authorized under the permit or license.

C. *License Amendments.* The elimination by this rule of the financial qualifications review for electric utility applicants also applies to any electric utilities that become co-owners via amendments to existing permits or licenses. From time to time, original owners of production or utilization facilities make arrangements to transfer to other electric utilities a portion of the ownership in the facility. Normally, an amendment request is then filed, which seeks to add the new partner as co-owner and co-licensee. For the purposes of this rule, similar to the situation relating to prelicensing antitrust review of these new owners, the amendment request comprises the initial license application by the new, prospective co-owner, even though the amendment request may actually be filed by the present licensee and owner. *E.g., Detroit Edison Company* (Enrico Fermi Atomic Power Plant, Unit No. 2), ALAB-475, 7 NRC 752, 755, n.7 (1978). Since the same financial qualifications review considerations apply to all electric utility applicants, regardless of the particular manner in which their application is tendered to the NRC, it should be clear that this final rule applies to any request for an amendment that would, if granted, include a new electric utility as a co-owner and co-licensee in a production or utilization facility.

IV. Conclusion

In summary, the Commission has concluded that the adoption of the rule will substantially reduce the effort and resources associated with demonstrating financial qualifications of electric utilities that are applying to construct and operate nuclear production and utilization facilities without reducing the protection of the public health and safety. This portion of the rule will be effective immediately upon publication, pursuant to 5 U.S.C. 533(d)(1), since the rule is expected to relieve significantly the obligation of certain applicants with respect to information required for construction permits and operating licenses, and also to reduce the amount of unnecessary, time-consuming staff review and adjudicatory proceedings. Although the rule will be applied to ongoing licensing proceedings now pending and to issues or contentions therein, *Union of Concerned Scientists* v. *AEC*, 499 F.2d 1069 (D.C. Cir. 1974), it should be clear that the NRC neither intends nor expects that the rule will affect the scope of any issues or contentions related to a cost/benefit analysis performed pursuant to the National Environmental Policy Act of 1969, either in pending or future licensing proceedings for nuclear power plants. Under NEPA, the issue is not whether the applicant can demonstrate reasonable assurance of covering certain projected costs, but weather is merely what costs to the applicant of constructing and operating the plant are to be put into the cost-benefit balance. As is now the case, the rule of reason will continue to govern the scope of what costs are to be included in the balance, and the resulting determinations may still be the subject of litigation. Thus, financial qualifications would not be expected to become an issue or contention in an NRC licensing proceeding insofar as NEPA might be involved.

The Commission has also concluded that adoption of the on-site property damage insurance requirement, as modified, will better ensure that adequate protection of the health and safety of the public is achieved. This requirement will be effective June 29, 1982.

Paperwork Reduction Act Statement

The Nuclear Regulatory Commission has submitted this rule to the Office of Management and Budget for such review as may be appropriate under the Paperwork Reduction Act of 1980 (Pub. L. 96–511). The date on which the information collection requirements of this rule become effective, unless advised to the contrary, accordingly, reflects inclusion of the 60 day period which the Act allows for such review.

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the NRC hereby certifies that this rule will not have a significant economic impact on a substantial number of small entities. The rule reduces certain minor information collection requirements on the owners and operators of nuclear power plants licensed pursuant to sections 103 and 104b of the Atomic Energy Act of 1954, as amended, 42 U.S.C. 2133, 2134b. These electric utility companies are dominant in their service areas. Accordingly, the companies that own and operate nuclear power plants are not within the definition of a small business found in section 3 of the Small Business Act, 15 U.S.C. 632, or within the Small Business Size Standards set forth in 13 CFR Part 121.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and section 553 of Title 5 of the United States Code, the following amendments to 10 CFR Parts 2 and 50 are published as a document subject to codification.

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47 FR 16005
Published 4/14/82

10 CFR Part 2

General Statement of Policy and Procedure for Enforcement Actions; Correction

AGENCY: Nuclear Regulatory Commission.

ACTION: Revised general statement of policy; correction.

SUMMARY: This document corrects a revised general statement of policy on enforcement action published in the **Federal Register** of Tuesday, March 9, 1982, (47 FR 9987). The action is necessary to correct two statements and make other changes in column headings and footnotes.

FOR FURTHER INFORMATION CONTACT: James Lieberman, Acting Director, Enforcement Staff, Office of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, (301) 492–4909.

SUPPLEMENTARY INFORMATION: The revised general statement of policy published in the Federal Register on March 9, 1982, (47 FR 9987) is corrected as follows:

1. On page 9989, middle column, the statement, "(2) provision that severity level III violations be considered for civil penalties, rather than normally assessing civil penalties for them;" is changed to read, "(2) provision that severity level III violations be considered for civil penalties but not necessarily imposed in every instance of a severity level III violation;".

2. On page 9989, third column, second paragraph under "I. Introduction and Purpose," the sentence, "It is the Commission's intent that noncompliance should be more expensive than compliance." should be inserted to appear immediately following the first sentence which begins, "Consistent with * * *".

3. On page 9992, "Table 1A.—Base Civil Penalties," first column of Table, "openings" is corrected to read "operations".

4. On page 9992, "Table 1A.—Base Civil Penalties," Footnotes 2 and 3, insert the word "Also" immediately before "Type" in each footnote.

5. On page 9994, first column, fourth line down, "B. Severity I" is corrected to read "B. Severity II".

Dated at Washington, DC, this 8th day of April, 1982.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,
Secretary of the Commission.

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47 FR 17797
Published 4/26/82

10 CFR Part 2

Implementation of Commission's Delegation of Authority To Determine Whether There Have Been Significant Changes in Operating License Applicant's Activities or Proposed Activities Since the Construction Permit Antitrust Review; Correction

AGENCY: Nuclear Regulatory Commission.

ACTION: Correction.

SUMMARY: In a Federal Register Document published on March 9, 1982 (47 FR 9983), the NRC amended its regulations under 10 CFR 2.104, Notice of hearing. The amendatory language of instruction #8 refers to § 2.104(d)(3). This document corrects this designation to § 2.104(d)(4) in the instruction and the regulatory text.

FOR FURTHER INFORMATION CONTACT: John D. Philips, Chief, Rules and Procedures, Office of Administration, Nuclear Regulatory Commission, Washington, DC 20555, (301) 492–7086.

Dated at Washington, DC, this 21st day of April 1982.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,
Secretary of the Commission.

47 FR 40535
Published 9/15/82
Effective 9/15/82

10 CFR Part 2

Commission Review Procedures for Power Reactor Construction Permits and Operating Licenses; Immediate Effectiveness Rule

AGENCY: Nuclear Regulatory Commission.

ACTION: Interpretative rule.

SUMMARY: The Nuclear Regulatory Commission is amending its so-called "immediate effectiveness rule" to clarify the weight of authority to be accorded Commission effectiveness decisions by its Licensing and Appeal Boards conducting subsequent reviews of stay requests or of the merits of applications for construction permits or operating licenses. The Commission confirms its intention that, absent express instructions to the contrary, no statement made in the course of its effectiveness determination is to be given any weight by the Licensing or Appeal Boards in their review of stay requests or of the merits of the license or permit applications.

EFFECTIVE DATE: September 15, 1982.

FOR FURTHER INFORMATION CONTACT: Richard A. Parrish, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, (202) 634–3224.

SUPPLEMENTARY INFORMATION: Pursuant to 10 CFR 2.764, the Commission conducts an informal review of each Atomic Safety and Licensing Board decision that authorizes the Director of NRC's Office of Nuclear Reactor Regulation to issue a construction permit or a full power operating license for a nuclear power reactor. The purpose of this informal Commission review is to determine whether significant safety issues exist that warrant staying the effectiveness of the Licensing Board decision, in effect withholding the permit or license, pending the appellate review of the merits of the Licensing Board decision by the Atomic Safety and Licensing Appeal Board or the Commission. The Commission's effectiveness review was never intended to be a detailed, formal review of the record developed before the Licensing Board. Rather, this informal and expedited review focuses upon significant issues of public health and safety, especially those related to regulatory developments subsequent to the accident at Three Mile Island. The effectiveness review was intended to be conducted entirely separate from review of any stay requests filed under 10 CFR 2.788 and formal appellate review under 10 CFR 2.762 and 2.786.

In the recent review of a Licensing Board decision that authorized the issuance of a full-power operating license for the McGuire Nuclear Station, the Appeal Board questioned what role an intervening Commission effectiveness decision should play in the Appeal Board's review of the merits of the Licensing Board decision. *Duke Power Company* (William B. McGuire Nuclear Station, Units 1 and 2), ALAB–669, 15 NRC 453, 485–486 (March 30, 1982). The Commission had allowed the Licensing Board decision to become effective, thereby authorizing issuance of the license in question, but had attached conditions to the license as a result of its effectiveness review. CLI–81–15, 14 NRC 1 (1981). The rule currently provides that the Commission's effectiveness review is without prejudice to subsequent reviews of the Appeal Board and the Commission. 10 CFR 2.764(f)(2)(v). However, the rule also provides that the Commission may give instructions as to the future handling of the proceeding, including furnishing policy guidance with respect to particular issues. 10 CFR 2.764 (f)(2)(iv).

The Commission has decided to provide the following clarifying guidance regarding the relevance of Commission effectiveness decisions to subsequent Licensing and Appeal Board reviews of stay requests or the merits of license or permit applications. Unless the Commission otherwise explicitly so directs in its immediate effectiveness determination, no statement made in the course of the opinion or statement reflecting that determination is to be given any weight by the Appeal Board in its consideration of either a stay motion under 10 CFR 2.788 or an appeal on the merits under 10 CFR 2.762 or by the Licensing Board in any subsequent formal adjudicatory proceedings.

This amendment to the immediate effectiveness rule clarifies the Commission's original intent regarding the weight to be accorded the Commission's effectiveness decisions. It does not affect the parties' rights of participation in adjudicatory licensing proceedings. Nor does it affect the method or standards of review employed by the Commission in conducting its effectiveness review, the availability of stays pursuant to 10 CFR 2.788, or the subsequent Appeal Board and Commission review of the merits of Licensing Board decisions. Because this amendment is an interpretative rule, the Commission has determined to forego notice and comment procedures of the Administrative Procedure Act (5 U.S.C. 553) and make it effective upon publication in the **Federal Register.**

Separate Views of Commissioner Roberts

I believe the Commission's action in adopting this rule on immediate effectiveness is premature. I believe the Commission's recent decision to vote twice (once on contested issues in the licensing proceeding, a second time on uncontested issues) prior to issuing a license is also premature. Both of these decisions were made by the Commission prior to receipt of recommendations from the Regulatory Reform Task Force. This group was established by the Commission to review Part 2 of the Commission's Rules and to make recommendations indicating how the licensing process might be made consistent and efficient. Rather than wait for these recommendations, the Commission has made several piecemeal changes in existing regulations and internal Commission procedures, such as the two described above. This would seem to make the job of the Regulatory Reform Task Force more difficult as the rules and process it is reviewing are changing while it reviews them. Further, such action seems shortsighted as the Commission may adopt rules in the future, based on the Task Force's recommendations, which change the rules and internal procedures being adopted now.

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission hereby certifies this rule will not have a significant economic impact on a substantial number of small entities. The rule clarifies the Commission's Rules of Practice by describing the weight of authority to be accorded the Commission's effectiveness decisions.

Paperwork Reduction Act Statement

This final rule contains no new or amended recordkeeping, reporting, or application requirement or any type of information collection requirement subject to the Paperwork Reduction Act (Pub. L. 96–511).

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and section 553 of Title 5 of the United States Code, the following amendment to Title 10, Chapter I, Code of Federal Regulations, Part 2, is published as a document subject to codification.

List of Subjects in 10 CFR Part 2

Administrative practice and procedure, Antitrust, Byproduct material, Classified information, Environmental protection, Nuclear materials, Nuclear power plants and reactors, Penalty, Sex discrimination, Source material, Special nuclear material, Waste treatment and disposal.

The authority citation for this document is:

Authority: Sec. 161, Pub. L. 83–703, 68 Stat. 948, as amended (42 U.S.C. 2201).

47 FR 47802
Published 10/28/82
Effective 10/28/82

10 CFR Part 2

Delegation to Commission Secretary

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations to allow the Commission's Secretary to perform certain functions previously performed by the Commission itself. Specifically, these amendments will allow the Secretary to rule on certain requests for hearings, to refer certain requests for hearings to the Atomic Safety and Licensing Board Panel, and to take action on minor procedural matters. These amendments will allow the Commission to act on these matters more expeditiously.

EFFECTIVE DATE: October 28, 1982.

FOR FURTHER INFORMATION CONTACT: Michael B. Blume, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone: 202/634-3224.

SUPPLEMENTARY INFORMATION:

I. Background and Action Taken

Under section 201(a)(1) of the Energy Reorganization Act of 1974, 42 U.S.C. 5841(a)(1), the Commission is required to meet to take formal actions. This has required the Commission to meet to dispose of non-substantive hearing requests, and to perform certain other minor ministerial functions. Both to minimize time spent on minor matters and to expedite the decisional process by eliminating the need for a Commission meeting, the Commission has previously delegated certain functions to its Secretary, who has the authority to act for it. 10 CFR 2.772. The Secretary is thus authorized, among other things, to rule on certain requests for extensions of time to file pleadings. 10 CFR 2.772(b). The Commission has decided to transfer additional authority to the Secretary, who shall act after consulting with the General Counsel and the Commission. Therefore, the Commission is amending 10 CFR 2.772 to allow the Secretary to:

1. Deny hearing requests which both fail to comply with the Commission's pleading requirements and fail to raise genuine issues. The Secretary will now, for example, be able to dispose of requests for hearings on matters not within the Commission's jurisdiction *and* not containing allegations of interest required by 10 CFR 2.714.
2. Refer requests for hearings, where the requester is entitled to a hearing as a matter of right, to the Atomic Safety and Licensing Board Panel or an Administrative Law Judge. This will allow the Secretary, for example, to refer to the Licensing Board Panel requests for hearings by licensees in response to Commission orders to show cause. *See* 10 CFR 2.202(c).
3. Rule on minor procedural matters.

II. Statement Regarding Notice and Comment

Because these amendments concern minor procedural matters, i.e., rules of agency procedure and practice, good cause exists for finding that the notice-and-comment procedures of the Administrative Procedures Act, 5 U.S.C. 553, are unnecessary and for making the amendment effective on publication in the **Federal Register.**

III. Statement Regarding Paperwork Reduction Act

These amendments dealing with delegations of authority from the Commission to its Secretary have no application/reporting/recordkeeping or other information collection requirements and, as such, are not subject to the requirements of the Paperwork Reduction Act of 1981, 44 U.S.C. 3501–3520.

IV. List of Subjects in 10 CFR Part 2

Administrative practice and procedure, Antitrust, Byproduct material, Classified information, Environmental protection, Nuclear materials, Nuclear power plants and reactors, Penalty, Sex discrimination, Source material, Special nuclear material, Waste treatment and disposal.

The authority citation for this document is: Sec. 161, Pub. L. 83–703, 68 Stat. 948, as amended (42 U.S.C. 2201).

For the reasons set forth in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552, 553, the Nuclear Regulatory Commission adopts the following amendments to 10 CFR Part 2, published as a document subject to codification.

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47 FR 56314
Published 12/16/82
Effective 12/16/82

10 CFR Parts 2 and 9

Nomenclature Changes To Implement Executive Order 12356

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations to incorporate references to Executive Order 12356, "National Security Information," and its Implementing Directive that were issued by the Information Security Oversight Office (ISOO). E.O. 12356 supersedes E.O. 12065.

EFFECTIVE DATE: December 16, 1982.

FOR FURTHER INFORMATION CONTACT: Richard A. Dopp, Security Policy Branch, Division of Security, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone (301) 427-4415.

SUPPLEMENTARY INFORMATION: On April 2, 1982, the President issued E.O. 12356, "National Security Information," that supersedes E.O. 12065. This new E.O. 12356 and its Implementing Directive, published by ISOO, became effective August 1, 1982.

The Nuclear Regulatory Commission is amending portions of 10 CFR Parts 2 and 9 to substitute references to E.O. 12356 and its Implementing Directive for previous E.O. 12065 (and in the case of Part 2, its antecedent, E.O. 11652, "Classification and Declassification of National Security Information and Material") and its Implementing Directive. All other aspects and procedures of Part 2, Subpart I, and Part 9, Appendix A, remain unchanged.

Because these amendments relate solely to minor reference matters and do not impose obligations on the public, good cause exists for omitting notice of proposed rulemaking and public procedure thereon, as unnecessary, and for making the amendments effective on December 16, 1982 without the customary 30 days notice.

Paperwork Reduction Act Statement

This final rule contains no new or amended requirements for recordkeeping, reporting, plans, applications, or any other types of information collection subject to the Paperwork Reduction Act of 1980, Pub. L. 96–511 (44 U.S.C. 3501, et seq.).

List of Subjects

10 CFR Part 2

Administrative practice and procedure, Antitrust, Byproduct material, Classified information, Environmental protection, Nuclear materials, Nuclear power plants and reactors, Penalty, Sex discrimination, Source material, Special nuclear material, Waste treatment and disposal.

10 CFR Part 9

Freedom of information, Penalty, Privacy, Reporting requirements, Sunshine Act.

(Sec. 161, Pub. L. 83–703, 68 Stat. 948, as amended (42 U.S.C. 2201), and Sec. 201, Pub. L. 93–438, 88 Stat. 1242 (42 U.S.C. 5841))

Under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552 and 553, the following amendments to 10 CFR Parts 2 and 9 are published as a document subject to codification.

47 FR 57446
Published 12/27/82
Effective dates:
10 CFR 20.311 of Part 20 effective date is 12/27/83; 10 CFR Part 61 and all other changes effective 1/26/83.

Licensing Requirements for Land Disposal of Radioactive Waste

See Part 61 Statements of Consideration

48 FR 14873
Published 4/6/83.
Effective date: 5/6/83.

The Commission invites comments on this interim final rule by 5/6/83. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

Notice and State Consultation

See Part 50 Statements of Consideration

≫ 48 FR 44170
Published 9/28/83
Effective date: 10/28/83

10 CFR Part 2

Authority to Issue Notices of Violation to Non-Licensees and Delegation of Authority to Regional Administrators

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations to reflect its existing legal authority to issue a notice of violation to any person subject to the jurisdiction of the Commission, including a non-licensee. The amendment requires those persons to reply formally to a notice of violation. In addition, the amendment codifies the authority of Regional Administrators to issue notices of violation.

EFFECTIVE DATE: October 28, 1983.

FOR FURTHER INFORMATION CONTACT: Jane A. Axelrad, Director of Enforcement, Office of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone (301) 492–4909.

SUPPLEMENTARY INFORMATION: On November 15, 1982, the Nuclear Regulatory Commission published in the **Federal Register** (47 FR 51402) a notice of proposed rulemaking containing proposed amendments to 10 CFR Part 2. The amendments would codify the Commission's legal authority to issue a notice of violation to any person subject to the jurisdiction of the Commission, including a non-licensee, and would require that person to reply formally to the notice of violation. In addition, the amendments would codify the authority of Regional Administrators to issue notices of violation.

As presently written, § 2.201 of the Commission's regulations, "Notice of violation," provides for issuance of notices of violations to NRC licensees. In general, the Commission's regulatory authority is limited to NRC licensees or persons who are required to obtain a license under the Atomic Energy Act of 1954, as amended, or the Energy Reorganization Act of 1974 (ERA). However, in some regulatory areas, the Congress has extended the Commission's statutory authority to include non-licensees as well as licensees. For example, pursuant to section 206 of the ERA, 42 U.S.C. 5846, and the Commission's implementing regulation, 10 CFR Part 21, "Reporting of Defects and Noncompliance," persons who supply components important to the safety of facilities or activities licensed by the NRC are subject to certain reporting and related requirements intended to ensure that the Commission is promptly informed of defects in such components.

Section 206(d) of the Energy Reorganization Act specifically authorizes the Commission to conduct reasonable inspections and other enforcement activities needed to ensure compliance. The Commission has, on a case-by-case basis, required non-licensees to respond in writing to notices of noncompliance issued under the authority of section 206(d) of the ERA. However, as noted above, this authority is not currently reflected in 10 CFR 2.201 even though non-licensees are subject to Section 206 of the ERA and the Commission's implementing regulations.[1]

To correct this discrepancy, the Commission is amending §§ 2.200 and 2.201 of its regulations to specifically authorize the issuance of notices of violation to any person subject to the jurisdiction of the Commission, including nonlicensees. These amendments specify that a notice of violation issued to a non-licensee subject to the jurisdiction of the Commission will require a written explanation in accordance with the existing provisions of § 2.201 (a) and (b).

In addition, the functions of the Commission's Regional Offices have been upgraded in NRC Manual Chapter 0128 (a copy of which is available for inspection at the NRC Public Document Room at 1717 H Street NW., Washington, D.C.) to provide enhanced responsibilities and duties to the position of Regional Administrator. Section 027 of Manual Chapter 0128 authorizes the Regional Administrator to issue notices of violation. (Formerly, the Regional Offices were headed by Regional Directors and these Directors were delegated authority by the Commission to issue notices of violation. This authority had not been expressly codified in the regulations.)

Therefore, the Commission is amending its regulations to expressly provide that Regional Administrators or their designees are authorized to issue notices of violation under § 2.201.

The **Federal Register** notice provided a 30-day period for public comment. The Commission received six (6) comments in response to the notice. Copies of these comments may be examined in the Commission's Public Document Room at 1717 H Street NW., Washington, D.C. The NRC response to the comments is provided below.

Several of the commenters questioned the use of the phrase "person subject to the jurisdiction of the Commission" to describe those non-licensees affected by this rulemaking. One commenter wanted to specifically exclude utility employees. One argued that since section 234 of the Atomic Energy Act does not apply to non-licensed employees of power reactor licensees, the Commission should state that it intends to issue notices of violation only to employees specifically subject to Commission jurisdiction. One commenter wanted to delete all references to persons because whereas the licensee accepts regulation by applying for a license, the non-licensee does not.

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[1] The regulations do, however, allow the imposition of civil penalties, a more severe form of enforcement action, on non-licensees. *See* 10 CFR 2.200.

The Commission's intent in utilizing the phrase "any person subject to the jurisdiction of the Commission" is to describe those entities, in addition to those licensed by the Commission, which must comply with certain regulations promulgated by the Commission pursuant to its statutory authority. Although "person" is broadly defined in 10 CFR 2.4(o), the final rule authorizes enforcement actions against only those non-licensed persons who fall within the scope of the Commission's statutory authority. A significant source of statutory authority over such non-licensees is section 206 of the ERA (42 U.S.C. 5846). Section 206 places a statutory obligation upon those entities working in the nuclear industry, including entities supplying basic components, to identify and report defects in those components to the NRC. Moreover, section 206(d) authorizes the NRC to conduct enforcement activities as needed to insure compliance with its provisions. Because 10 CFR Part 21 of the Commission's regulations, entitled "Reporting of Defects and Noncompliance," implements section 206, it is primarily Part 21 violations for which the NRC will issue notices of violation against non-licensees.

By promulgating this rule change, the Commission simply intends to formalize the procedure for taking enforcement action under its present authority. It is not the intent of the rule to expand that authority. The Commission does not view the final rule as a departure from its present enforcement policy, but rather as a codification of current practice. The staff has issued notices to non-licensees in violation of Part 21 reporting requirements for a number of years. The final rule merely conforms the Commission's regulations to this practice. However, the Commission's emphasis on section 206 of the Energy Reorganization Act and Part 21 should not be read to restrict to those provisions the Commission's authority to issue notices of violation under the final rule. For example, a notice of violation might also be issued for violations of section 210(a) of the ERA (42 U.S.C. 5851(a)), which prohibits discrimination against employees for contacting, or attempting to contact, the Commission. Accordingly, the Commission will issue notices of violation against non-licensees in appropriate cases when requirements directly imposed upon non-licensees are violated. This view is consistent with previously stated Commission policy. *See* General Statement of Policy and Procedure for Enforcement Actions, 47 FR 9987, 9991 n.3 (March 9, 1982) (Enforcement Policy).

Several commenters asserted that the proposed rule change is unnecessary, pointing to the success of voluntary compliance and the ability of the Commission to exert its authority over licensees to ensure that non-licensee contractors comply with the applicable NRC regulations. While the Commission acknowledges the advantages of voluntary compliance, as well as of licensees taking an active role in ensuring that their contractors comply with NRC requirements, the Commission needs to be able to issue notices of violation against non-licensees in appropriate cases. The notice of violation serves not only to identify noncompliance with an NRC requirement, but also to require the recipient to identify the corrective action it will take in response to the noncompliance. Section 2.201, in its present and revised versions, requires the recipient of a notice of violation to respond to the notice by describing: (1) Corrective steps taken and results achieved; (2) corrective steps to be taken; and (3) the date when full compliance with NRC requirements will be achieved. By compelling a non-licensee subject to NRC regulations to describe the remedial action it has taken or will take to correct a violation, the Commission seeks to prevent recurrence of similar violations. The authority to issue a notice of violation against a non-licensee directly would also be particularly effective in cases where the non-licensee supplied a defective component to numerous licensees. By taking enforcement action against the non-licensee, the Commission would not necessarily need to take enforcement action against each licensee using the defective component, nor be forced to take enforcement action against one particular licensee.

Two commenters maintained that the proposed rule would not provide greater incentive for compliance with section 206 of the ERA. The Commission disagrees. Documenting a non-licensee's violation through issuance of a notice of violation is expected to provide greater incentive for compliance with NRC requirements. A notice of violation calls a licensee's attention to potential problems with the work of a particular non-licensee.

Several commenters cautioned the Commission against taking action which could infringe upon the rights of individuals. One commenter pointed to section 223(b), a criminal provision of the Atomic Energy Act, to illustrate both the inappropriateness of requiring admissions from natural persons and the potential for criminal sanctions as a result of failing to respond to a notice of violation issued pursuant to § 2.201. Another commenter, in urging deletion of all references in the new rule to persons subject to the jurisdiction of the Commission, felt that violations by non-licensees should be governed by § 2.205 of the Commission's regulations. This commenter viewed § 2.205 as affording a "greater semblance of due process" to non-licensees than provided by the amendment to § 2.201.

The Commission acknowledges that enforcement actions against individuals will be determined on a case-by-case basis, as provided in the Enforcement Policy. *See* 47 FR 9987, 9991 (March 9, 1982). Although § 2.205 of the Commission's regulations would appear to provide greater procedural protections, it should be recognized that § 2.205 sets forth the procedure for imposition of civil monetary penalties, an enforcement action which differs from that of issuing notices of violation and for which greater procedural protections are appropriate. The present rulemaking is concerned only with § 2.201, and the Commission believes that the procedural protections in that section are adequate.

In responding to concerns regarding criminal sanctions, the Commission notes that § 2.201 is a civil provision. An individual engaged in an activity for which a notice of violation could be issued under the Commission's statutory authority would be required to respond to the notice. Section 223(b) of the Atomic Energy Act provides for criminal liability only when knowing and willful violations of the Atomic Energy Act—or rules, regulations or orders issued thereunder—are committed. The mere issuance of a notice of violation does not mean that criminal sanctions would be appropriate.

Several comments were also submitted concerning the delegation of authority to Regional Administrators or their designees to issue notices of violation against both licensees and non-licensees. One commenter supported the delegation as to notices of violation directed against licensees, but opposed regional issuance of notices of violation against non-licensees, citing in support of its position the need for centralized control. Another commenter opposed any such delegation to the Regional Administrators, fearing inconsistent application of policy among the five NRC regions.

The Commission notes that as a practical matter, enforcement action against non-licensees is currently centralized in the NRC Region IV office, which is charged with implementation of the vendor program. The bulk of non-licensees subject to NRC jurisdiction are within this program. Most, if not all, notices of violation to be issued against non-licensees can be expected to originate from Region IV. As a result, no substantially greater uniformity would be achieved by having the Director of the Office of Inspection and Enforcement issue notices of violation against non-licensees. In responding to comments concerning delegation of duties to the Regional Administrators, the Commission notes that the NRC Regional Administrators have routinely issued notices of violation for the last several years. The final rule merely codifies this delegation of authority. However, the Director of the Office of Inspection and Enforcement is responsible for the Commission's enforcement program. Therefore, a non-licensee who has been issued a notice of violation and believes it has been unfairly treated may seek review with the Director. *See* Policy Statement on Regionalization, 48 FR 12619 (March 25, 1983).

Paperwork Reduction Act Statement

The collection of information this final rule contains is exempt from the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3518(c)(1)).

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission hereby certifies that this rule would not have a significant economic impact on a substantial number of small entities. Non-licensees subject to NRC jurisdiction have been required, on a case-by-case basis under the authority of section 206(d) of the ERA, to respond to violations of NRC requirements to assure that the Commission has adequate information concerning corrective action to carry out its statutory responsibilities. This rule is designed to formalize the current practice.

List of Subjects in 10 CFR Part 2

Administrative practice and procedure, Antitrust, Byproduct material, Classified information, Environmental protection, Nuclear materials, Nuclear power plants and reactors, Penalty, Sex discrimnation, Source material, Special nuclear material, Waste treatment and disposal.

For the reasons set out in the preamble and pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552 and 553, the Commission is adopting the following amendments to 10 CFR Part 2, which are published as a document subject to codification.

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48 FR 46489
Published 10/13/83
Effective 11/14/83

10 CFR Parts 2 and 50

Temporary Operating Licenses

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Commission is adopting amendments to its "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR Part 2 and to its regulations in 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," providing for the issuance of temporary operating licenses for nuclear power reactors. Pub. L. 97–415, enacted on January 4, 1983, amended section 192 of the Atomic Energy Act of 1954 (the Act), to authorize the NRC to issue such licenses. Section 192, initially added to the Act on June 2, 1972, authorized the Atomic Energy Commission (AEC) to issue temporary operating licenses for nuclear power reactors under certain prescribed circumstances. (The AEC's licensing authority was transferred to the NRC in 1975.) The authority under the original section 192 expired, however, on October 30, 1973. To the extent that the amended section 192 is in substance the same as the original section, the implementing regulations in the amendments to Parts 2 and 50 are also similar in substance to the now expired regulations which were initially published in 1972 to implement the section. The amendments to Parts 2 and 50 set out below are designed to conform Commission regulations and procedures to the new temporary operating licensing authority.

EFFECTIVE DATE: November 14, 1983.

ADDRESSES: Copies of comments received on the amendments and of the documents described below may be examined in the Commission's Public Document Room at 1717 H Street, NW., Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Thomas F. Dorian, Esq., Office of the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 Telephone: (301) 492–8690.

SUPPLEMENTARY INFORMATION: The supplementary information below is divided into three sections. The first sets out the background for the rule. The second responds to the comments on the proposed rule. And the third section describes the provisions of the final rule.

I. Background

After the March 1979 accident at the Three Mile Island nuclear power plant, the NRC focused its attention on evaluating the accident and its implications for the safe regulation of nuclear power in this country and on developing the necessary regulatory improvements for continued operation of nuclear power plants. During this period, construction continued on those nuclear power plants with construction permits, although NRC applied only very limited effort to preparing and meeting the necessary safety reviews and hearing requirements for the issuance of operating licenses for these facilities. Largely as a result of this state of affairs, in late 1980 it was argued that there was a possibility that delays would occur between the time when construction of some of these plants would be sufficiently completed to allow fuel loading and the start of operations and the time when all requirements for the issuance of operating licenses (including the hearing requirements of the Atomic Energy Act would be met.

Under the Atomic Energy Act of 1954, as amended (the Act), no person may operate a nuclear power plant without first obtaining an operating license from the NRC. A formal on-the-record evidentiary hearing must be held—and a decision rendered on the basis of that record—if requested by any person whose interest may be affected, before the Commission may issue an operating license. Before the enactment of Public Law 97–415, in a case where a hearing is held, the Commission lacked the authority to authorize fuel loading and low-power operation and testing on the basis of its safety and environmental evaluation; a utility was required instead to await authorization in the course of the hearing process. *See* 10 CFR 50.57(c).

It was argued that, notwithstanding the administrative changes to the licensing process designed to reduce the time required to complete the licensing of these plants, there remains a possibility that some licensing delays might occur for some of the plants scheduled to be completed in the near futures. In order to obviate the possibility of such delays ever occurring, on March 18, 1981, the Commission submitted a legislative proposal to amend the Act so as to authorize the Commission to issue a temporary operating license for a nuclear power plant, allowing operation and testing, in advance of the conduct or completion of an on-the-record evidentiary hearing on contested issues relating to the final operating license. Public Law 97–415 is the final legislative product of the Commission's proposal. It is an "extraordinary and temporary cure for an extraordinary and temporary situation." Conf. Rep. No. 97–884, 97th Cong., 2d Sess. at 35 (1982).

II. Responses to Public Comments on Proposed Rule

The Commission published a proposed rule in the **Federal Register** on April 16, 1983 for 30-days public comment (48 FR 14926). Thirteen commenters commented on the proposed rule. Six of the 13 commenters generally supported the rule and seven opposed it. The strongest and principal opposition came from commenters that thought that Long Island Lighting Company's Shoreham nuclear power plant is perhaps the sole candidate for a temporary operating license.

The comments and responses can be separated into the categories discussed below (a fuller analysis is provided in the response to comments available in the Public Document Room):

A. Ex Parte and Separation of Functions

One of the most controversial topics was the Commission's position on the application of the *ex parte* rule and separation of functions to the temporary operating licensing process.

As proposed, Subpart C to 10 CFR Part 2, "Procedures Under Section 192 for the Issuance of Temporary Operating Licenses," would simply have added procedural requirements to 10 CFR Part 2 needed to implement the temporary operating licensing authority in section 192 of the Act, as provided for in a new § 50.57(d) of 10 CFR Part 50. Unlike the hearing process on the final operating license, the legislation makes clear that the temporary operating licensing process would not be subject to the hearing requirements of section 189a. of the Act; thus, the process need not be subject to the requirements of Subpart A or to all the requirements of Subpart G of the Rules of Practice in 10 CFR Part 2. As explained in the preamble of the proposed rule, the Commission decided, however, that certain sections of Subpart G would be applied to resolve needless controversy about such items as the filing of papers, service on parties, and so on. These were 10 CFR 2.701, 2.702 and 2.708–2.712, relating to service and filing of documents, maintaining a docket, and time computations and extentions; § 2.713, relating to appearance and practice before the Commission; § 2.758, generally prohibiting challenges to the Commission's rules; and § 2.772, generally granting the Commisson's Secretary the authority to rule on procedural matters.

It was noted in the preamble of the proposed rule that 10 CFR 2.719 and 2.780, relating to separation of functions and *ex parte* communications, would not apply. However, the Commission also noted that it is sensitive to the concern that the informal contacts that would be allowed thereby should not be extensive and that they should not result in significant data or argument that are both relied on by the Commission in its temporary operating licensing decision and unavailable to the parties for comment before the decision. It was thus stated that, if informal contacts do take place which provide significant data or argument and which are both relied on by the Commission and unavailable to the parties, then that data or argument will be made available for comment before the decision. The Commission's decision not to apply separation of functions and *ex parte* rules to temporary operating licensing reflected a preference not to apply rules intended for formal, trial type proceedings, and was based on the belief that operating licensing and temporary operating licensing proceedings on a given plant are separate proceedings for the purpose of application of the formal hearing requirements of the Administrative Procedure Act (APA). It was argued that the amendment to section 192 of the Act states that section 189a. of the Act does not apply to a temporary operating licensing proceeding; thus, if section 189a. does not apply, then the APA's formal hearing requirements do not apply either. It was also noted that the Commission's consideration of informal communications with the parties in an informal temporary operating licensing proceeding would not prevent the Commission from eventually considering, as necessary, issues arising from the formal operating licensing proceeding. And it was stated that information provided in the informal proceeding would not be used in the formal proceeding, unless it is formally included in the record.

In this context, the Commission also noted the Conference Committee's statement that, under section 192, the Commission cannot issue a temporary operating license before "all significant safety issues specific to the facility in question have been resolved to the Commission's satisfaction." *See* Conf. Rep. No. 97–884, 97th Cong., 2d Sess., at 35 (1982).

Two Commissioners disagreed with the Commission's position. Commissioner Asselstine stated in additional views to the **Federal Register** notice:

> I strongly disagree with the Commission majority's decision *not* to apply the provisions of 10 CFR Sections 2.719 and 2.780, relating to separation of functions and *ex parte* communications, as part of the procedural requirements for implementing the temporary operating license authority in Section 192 of the Atomic Energy Act of 1954, as amended.
>
> In all likelihood, the issues that will be raised before the Commission in the temporary operating license proceedings under the provisions of Section 192 will be similar to, or the same as, the issues being adjudicated in the hearing in the final operating license proceedings. By permitting the NRC staff and the applicant, among others, to make informal off-the-record contacts with the Commission on these issues during the temporary operating license proceedings, the Commission majority's proposed rule presents a grave risk of contaminating the formal on-the-record operating license proceeding. I do not believe that this risk of contaminating the final operating license proceeding can be avoided easily if informal, off-the-record contacts on similar issues arising in the temporary license proceedings are permitted. In order to assure procedural fairness in our operating license proceedings, I would apply our regulations relating to separation of functions and *ex parte* communications to temporary operating license proceedings, just as we now do for final operating license proceedings.

Commissioner Gilinsky also stated his separate views in the **Federal Register** notice:

> I have voted against the Temporary Operating License rule because of the Commission's decision to exempt Temporary Operating License proceedings from the *ex parte* and separation of functions rules. "This would mean that the Commission's staff, applicants and intervenors would be free to contact individual Commissioners as well as the Commission's Office of General Counsel and Office of Policy Evaluation to argue their respective position on the temporary operating license." (A sentence of explanation which appeared in the penultimate draft and which the Commission was too modest to leave in the final version.)
>
> This decision is but another example of the Commission's deep-seated hostility toward informing the public and involving it in NRC's proceedings. The decision is incompatible with the basic notions of fairness which underline the *ex parte* rules since the temporary operating license issues will inevitably be quite similar to the issues in the

> operating license hearing which will be going on at the same time. As has so often happened, the course chosen by the Commission is likely to be self-defeating: it is bound to result in endless litigation.

Comments. Three commenters supported the Commission's position. They argued that the decision was in accord with the legislation, that it would permit the Commission direct access to its staff, and that it would prevent delays.

Five commenters opposed the Commission's position. They argued, among other things, that it was a violation of due process, citing *Home Box Office*, 567 F. 2d 9 (D.C. Cir. 1977), *cert. denied*, 434 U.S. 809 (1977), and *United States Lines* v. *Federal Maritime Commission*, 584 F. 2d 519 (D.C. Cir. 1978); that the Commission's proposed safeguards to prevent tainting of the process were inadequate; that the operating license proceeding inevitably would be contaminated, since the issues and parties are likely to be identical; that the Commission's justification for suspending the *ex parte* rule was inadequate, being at best a vague preference for avoiding formal rules; that the Commission's assertion that it may permit *ex parte* contacts because the temporary operating license proceeding is not governed by the formal hearing requirements of the APA was unsound and illegal under such cases as *Home Box Office;* and, finally, that, though section 11 of the legislation specifies that a notice and comment format is to be used for temporary operating licenses, precluding argument about such hearing procedures as cross examination, its legislative history emphasizes the need for a "detailed procedural framework" to govern the process; this point, tied to the fact that the legislation expressly subjects the Commission's decision to judicial review, underscores the importance of strict adherence to all prevailing rules of administrative law except those expressly waived by the Act; in turn, this means that the APA's *ex parte* prohibitions should apply.

Response. The Commission has reviewed carefully both sides of the issue. Though it believes that the legislation gives it adequate flexibility to avoid subjecting the temporary operating licensing process to the formal, trial type hearing requirements of section 189a. of the Act, the Commission has decided to modify slightly its position about not applying the *ex parte* rule (§ 2.780) and separation of functions requirements (§ 2.719) to the temporary operating licensing proceeding.

The Commission's position, as set forth in § 2.305 of the final rule, is that, for the purpose of expeditiously acting on the petition for a temporary operating license, it continues to believe that it may need to communicate with its staff. However, oral communications between the Commission's staff and the Commissioners, members of their immediate staffs, or other NRC officials who advise the Commissioners, in the exercise of their quasi-judicial functions, on the merts of any substantive matter at issue in the temporary operating licensing proceeding will be distilled promptly in a fair, written summary, placed in the Commission's Public Document Room, and quickly made available to the parties in the proceedings. A copy of any written communication will also be placed in the Public Document Room and, similarly, quickly made available. These procedures will not apply to communications not prohibited by 10 CFR 2.780, such as status reports and discussions about generic health or safety problems.

Turning to the issue of communications from persons outside the Commission about substantive matters at issue in a temporary operating licensing proceeding, the Commission believes that the comments above as to the need for communications with the staff do not apply with equal force to communications with parties outside the Commission. Thus, the prohibitions of § 2.780 apply in the latter case. Therefore, the Commission will not entertain *ex parte* communications in this context, and persons outside the Commission wishing to communicate with the Commission will be required to use the normal comment procedures outlined in the final rule. If oral or written communications do occur, however, they will be treated using the procedures described in this comment response. The parties will be afforded an additional opportunity to comment to the extent that informal contracts do take place as described above, and such contacts provide significant new data or argument which the Commission proposes to rely upon in making its decision.

B. Emergency Planning

Section 50.57(d)(2) of the proposed rule provided, among other things, that the initial petition for a temporary operating license may be filed after the filing of a State, local or utility emergency prepardness plan for the facility.

Comments. Emergency planning was also a controversial topic. One commenter supported the proposed rule. This commenter first noted that the proposed rule does not directly address emergency planning requirements. Citing Cong. Rec. E 5057 and E 5060–61 (Dec. 10, 1982), the commenter then stated that the proposed rule is consistent with the legislation's history and with existing § 50.47(d).

Three commenters opposed the proposed rule. One commenter argued that the final rule should (1) explicitly state that a full Commission review of on-site and off-site emergency preparedness is a necessary prerequisite for issuance of a temporary operating license, (2) explains how the Commission will conduct its review, and (3) should set forth explicitly that the findings of the Federal Emergency Management Agency (FEMA), called for under § 50.47(a)(2), also must be received and evaluated by the Commission before it considers issuance of the temporary operating license.

Another commenter stated that NRC's existing regulations require the adoption of a local off-site radiological emergency response plan and that, in the absence of such a plan, no operating license could be issued simply on the basis of a utility plan. The commenter argued that, to the extent that the new § 50.57(d) is contrary to that existing regulatory requirement, the tempt to issue a temporary operating license would be directly at odds with the unavoidable fact that no operating license could be issued where no local off-site emergency plan exists. Thus, the "extraordinary remedy" of the temporary operating license would be useless and any attempt to use it would only result in a greater degree of litigation—not the expeditious licensing of a nuclear facility whose future is certain.

A third commenter argued that the proposed rule should specifically require (1) the filing of an off-site plan, (2) a finding that such a plan is implementable, and (3) require the performance of an acceptable exercise before operation above 5 percent power.

Response. The Commission believes that the proposed rule need not be modified. Neither the text of section 192 itself nor the legislative history cited by the commenters prohibits the Commission from applying 10 CFR 50.47(d) to temporary operating licenses for fuel loading and operation under 5 percent power. Further, more is involved in its decision to grant or deny a temporary operating license than, under new § 50.57(d)(2), the simple filing of a State, local, or utility emergency preparedness plan for the facility. Before the Commission can grant such a license, it must determine, *inter alia*, that "all requirements of law, other than the conduct or completion of any required hearing on the final operating license, are met" and that, "in accordance with such requirements, there is reasonable assurance that temporary operation of the facility, in accordance with the terms and conditions of the license, will provide adequate protection to the public health and safety and the environment." This means that 10 CFR 50.47(d) will apply to temporary operating licenses for fuel loading and operation under 5 percent power, and that § 50.47(a) will apply to temporary operating licenses for operation over 5 percent power. The Commission believes that it is unnecessary to repeat this in the rule itself.

C. Deadline for Requesting a Temporary Operating License

The proposed rule provided in § 2.301 that, because NRC's authority to issue new temporary operating licenses expires on December 31, 1983, an applicant seeking such a license must file its written petition by November 23, 1983.

Comments. Two commenters stated that the proposed filing deadline date is too near the expiration of NRC's authority to allow for publication of the petition in the **Federal Register**, for full response to the petition by interested persons, and for a fair and reasoned decision by NRC based on the information before it. One commenter therefore requested that the Commission change the deadline for filing a petition to October 15, 1983, and a second to October 1, 1983.

Response. The Commission agrees with the commenters that a more reasonable deadline date is needed for the filing of the applications, to include more time for its decision and to make more time available for the necessary procedural steps. The Commission debated whether to include a deadline based on a fixed amount of time before the applicant's need date, thereby guaranteeing adequate time for the necessary staff and Commission reviews. However, because its authority to issue a temporary operating license will expire relatively soon, it decided to set a fixed and certain date. The deadline of November 23, 1983 in § 2.301(a) has been changed to November 14, 1983, thereby allowing more time for the requisite activities and decisions. (*See* discussion below for additional reasons for extending the deadline.) It should be noted that proposed legislation is pending in Congress which would extend the Commission's authority to issue temporary operating licenses to September 30, 1985. (*See* H.R. 98–103, Part 2, at 1 and 17.) If the legislation is enacted, this rule will be changed accordingly.

D. Affidavits and Responsive Affidavits

The proposed rule provided for the filing of a petition by an applicant, accompanied by affidavits, and for responsive affidavits by interested parties. §§ 2.301, 2.302, 2.304, and 50.57(d)(3). Proposed §§ 2.303 and 50.57(d)(4) also provided that any person may file affidavits in support of, or in opposition to, the petition within 30 days after the publication of such notice in the **Federal Register**. This language is identical to that found in amended section 192a. of the Act. These provisions proved somewhat contentious and elicited various comments in four areas.

1. Possible NRC Staff Responsive Affidavits

Comment. One commenter noted that the staff is not required to file affidavits and stated that the final rule should specifically state whether or not the staff would file any documents (except the Safety Evaluation Report). The commenter also argued that, if the staff does file responsive affidavits, interested parties—including both the applicant and intervenors—should be permitted to respond to those affidavits.

Response. The Commission has rejected the comment. The staff may or may not wish to file a responsive affidavit under §§ 2.303, 2.304, and 50.57(d). It is not required to file one, though, if it does, it is required, just as any other party, to serve it on the parties to the proceeding.

As a separate matter, the Commission has clarified in §§ 2.303 and 2.304 that "responsive affidavits" can be filed either in support of or in opposition to the petition for a temporary operating license.

2. Thirty-day Response Period

Comments. The same commenter pointed out that the 30-day response period may not allow interested persons a real opportunity in some circumstances to participate in the temporary operating licensing proceeding. The commenter requested that the final rule should provide explicitly that the 30-day period for the filing of responsive affidavits may be extended where justified by factors such as the number or complexity of issues raised by the petition or the length of the affidavits involved.

In this same vein, another commenter requested the Commission either to forbid the applicant from submitting affidavits and other material in support of its application during the 30-day comment period (thereby perhaps flooding the Commission with supporting affidavits on the last day of the comment period and precluding public comment thereon) or to extend the comment period to allow 30 additional days in which post-application submissions by the applicant may be rebutted.

A third commenter believed it a mistake, as a matter of policy, that § 2.711, involving extensions and reductions of time limits, would apply, and requested the Commission to prescribe specifically the time within which a responsive affidavit may be filed, as it has with respect to affidavits in § 2.303.

Response. The three comments are rejected. The regulation simply follows the legislation which specifically provides for the 30-day comment period. The Commission expects an applicant to submit all relevant supporting information with its petition, to allow the Commission and its staff time to review that information and to provide an adequate response time to the public. Aside from the 30-day response period, the Commission would apply § 2.711 to the extent it believes necessary in the circumstances. It wishes to make clear though, and has modified the final rule accordingly, that the last 30-day response period will be initiated only after the applicant has filed its last document which provides substantive data or argument material to the granting of its application. If the applicant files such additional documents after it has filed its petition, these and the petition will be renoticed in the **Federal Register**, for the purpose of initiating a new 30-day period.

3. Responsive Affidavits: Material Facts and Necessary Findings

In describing the contents of affidavits that may be filed in response to a petition for a temporary operating license, proposed § 2.304 provided that such affidavits should state the "material facts as to which it is contended that there exists a substantial issue regarding the issuance of the temporary operating license."

Comments. A commenter requested the Commission to make clear that an opponent of the petition should be required to make a *prima facie* showing that the issues it seeks to raise involve "significant safety issues specific to the facility in question," and, similarly, requested that the Commission amend proposed § 2.304 to provide that the responsive affidavits be limited to those significant safety issues which have been raised in the final operating licensing proceeding.

Another commenter argued that the affidavits should do no more than repeat the contentions and the evidence at issue in the concurrent Atomic Safety and Licensing Board (ASLB) hearings, stating its belief that the ASLB is the proper forum to resolve the contentions before it in the first instance and that it would defeat the intent of Congress for the Commission to duplicate the ASLB's role.

Response. Both requests are rejected. The Commission believes that the prescribed standard is restrictive enough, considering the informal nature of the hearing. Any higher standard would cast the proceeding in the mold of an adjudicatory, trial type hearing. With respect to the second point raised by the commenter, the Commission expects that most and perhaps all of the responsive affidavits will involve significant safety issues previously raised; nevertheless, it does not wish to preclude anyone from raising new safety issues, if these concern material facts that are relevant to issuance of the temporary operating license and that must be resolved before the Commission can make the requisite three findings in § 50.57(d)(5).

4. Deadline on Commission Action.

On a related matter, proposed § 2.303 provided that the Commission will act "as expeditiously as possible" following the receipt of responsive affidavits to reach a determination on the petition.

Comment. A commenter argued that the Commission impose upon itself deadline of December 31, 1983, for acting on such petitions.

Response. The request is rejected. The Commission has moved the applicant's deadline for submitting its petition to October 15, thereby allowing everyone, including itself, time to take the necessary actions and to make the requisite decisions.

E. Definition of Requirements of Law

Proposed § 50.57(d)(5) set forth the findings that the Commission must make to issue or, subsequently, to amend a temporary operating license. The first required finding is that "in all respects other than the conduct or completion of any required hearing, the requirements of law are met."

Comment. A commenter noted that this provision simply repeats the language of amended section 192b.(i) of the Act. The commenter requested that the final rule make clear that the requirements of law include the Act, other applicable statutory provisions regarding nuclear power, and the NRC's regulations, particularly those in 10 CFR Part 50, promulgated pursuant to those laws.

Response. The request is rejected. The cited provision appears in many places in the Commission's regulations, *e.g.*, § 50.12(a). It is clear that the phrase refers to all applicable statutes and regulations.

F. Public Disclosure

The proposed rule excluding § 2.790 from being applied to a temporary operating licensing proceeding. That section provides, among other things, that NRC documents, in general, will be made available for inspection and copying.

Comment. A commenter argued that the Commission had made no attempt to justify exempting NRC documents concerning temporary operating licenses from disclosure and that the policy reasons behind the requirements of public disclosure embodied in § 2.790 should apply with equal or greater force to a temporary operating licensing proceeding.

Response. The comment is accepted. The Commission sees on valid reason for exempting NRC documents concerning temporary operating licenses from disclosure under the provisions of § 2.790.

G. Availability of Information

Proposed § 2.305(b) excluded NRC's rules regarding discovery from being applied to a temporary operating licensing proceeding. Instead, proposed § 2.302 provided for exchanges of information limited to affidavits, exhibits, and a list of documents relied upon to support the facts stated in the affidavit. The documents themselves would be made available only at a particular location.

Comment. A commenter stated that this list of documents may not provide adequate information to interested parties and requested that the rules should provide an expeditious mechanism by which interested parties can obtain documents, other than those listed by the applicant, which are important to the issues involved.

Response. The request is rejected. The Commission expects the applicant to submit or refer to all the necessary information for it to make an informed decision and for the public to be able to comment reasonably. Thus, all supporting documentation shall be available for inspection. Failure of the applicant do do so will result in denial of its application. (*See* also the response at paragraph D(2) above.) The commenter's request is simply another way of saying that it would like some form of discovery. Though the request appears reasonable, at first glance, the attendant administrative requirements would be too complex and would conflict with the need for expeditious proceedings.

H. Oral Argument

Proposed § 2.308 provided that, ordinarily, informal procedures will be used to resolve particular issues as they arise, i.e., ordinarily formal adjudicatory procedures would not be used.

Comments. A commenter requested that the final rule provid that the Commission will not deny an application for a temporary operating license without first giving the applicant a chance to make an oral presentation to the Commission.

Another commenter requested that the final rule should provide the Commission with discretion to order oral argument, where a major legal issue might be in controversy and the Commission would benefit from hearing parties' views on the matter and where the parties, having filed extensive affidavits, might comment orally on each other's filings.

A third commenter requested that the Commission delete the term "ordinarily" from the final rule, arguing that section 192b. provides that the requirements of section 189a. of the Act "shall not apply to the issuance or amendment of a temporary operating license" and that, therefore, Congress clearly intended that the Commission not use formal adjudicatory procedures in the issuance of temporary operating licenses.

Response. The three requests are rejected. Section 2.308 as proposed contained ample flexibility for the Commission to order oral argument, if it believes that it is necessary to the proper disposition of the proceeding. Moreover, under the legislation the Commission retains authority to choose among the procedures it wishes to apply to a temporary operating licensing proceeding. The term "ordinarily" was added to show that the Commission could use adjudicatory procedures to resolve particular issues.

I. Consideration of Commission Findings in Final Operating Licensing Proceeding

Proposed § 2.306 provided that no party shall argue the issuance or denial of a temporary operating license in support of its position in a proceeding for the issuance of a final operating license.

Comment. A commenter requested the Commission to clarify this provision to provide that, while the issuance of such a temporary operating license *per se* may not be used by a party in support of its position in a proceeding for the issuance of the final operating license, some Commission rulings contained in the final order authorizing the issuance of a temporary operating license may be used by any party in the final operating licensing proceeding.

Response. The request is rejected. A presiding ASLB in a formal, on-the-record adjudication should not be held to the Commission's findings in a short and expedited informal proceeding in which the issues may not have been fully briefed and argued.

J. Notification to the Commission

Proposed § 2.307 provided that any party to a hearing required pursuant to section 189a. of the Act shall promptly notify the Commission of any information that the terms and conditions of the temporary operating license are not being met or that those terms and conditions are not sufficient.

Comment. A commenter requested that the Commission require that such notice be made by affidavit and that it be accompanied by a statement of the material facts supporting the assertion. The commenter also requested that this provision afford the licensee an opportunity to respond by affidavit to any information provided to Commission pursuant to this provision.

Response. The request is accepted in part. The Commission agrees that a notification under § 2.307 should be accompanied by a statement of material facts and that a holder of a temporary operating license should be able to respond. Section 2.307 has been changed accordingly. The Commission, however, has rejected the request that the notification and response take the form of affidavits, because this requirement would add unnecessary formality.

K. Duration of License

Proposed §§ 2.301 and 50.57(d) (1) and (7) provided, among other things, that the Commission will limit the duration of a temporary operating license or an amendment to a "specified time."

Comment. A commenter stated that the specified time should in all cases be the date a full operating license is issued, arguing that issuance for a duration less that the time of the issuance of a full power operating license would only create a need to amend the license solely for the purpose of extending its duration.

Response. The request is rejected. The Commission agrees with the commenter that it could issue a temporary operating license that would continue in effect until a full power operating license is granted. The proposed section would not have barred the Commission from doing so. However, the rule does provide the Commission with the flexibility to issue the temporary operating license for a shorter time, if particular circumstances indicate that that is desirable or necessary.

III. Final Rule

A. Framework

A person applying for an operating license for a nuclear power plant, which is licensed under sections 103 or 104b. of the Act and as to which a hearing is otherwise required under section 189a. of the Act, could apply for a temporary operating license, pending final action by the Commission on the application for the final operating license. The temporary operating license for the facility would authorize fuel loading, testing and operation at a specific power level to be determined by the Commission. The initial petition would have to be limited to power levels not to exceed 5 percent of the nuclear facililty's rated full thermal power, and the Commission could not initially authorize a higher power level. After the temporary operating license is issued, the licensee may file one or more additional petitions with the Commission to allow facility operation up to full power in staged increases in power level beyond the initial 5 percent limitation. All authorizations for temporary operating licenses under section 192 and these implementing regulations must be pursuant to a vote and a final order of the Commission itself and cannot be delegated to the NRC staff. The authorizations themselves lie within the discretion of the Commission. This means, among other things, that the Commission in a temporary operating license would authorize both a given power level and the time it deems appropriate for operation at that level before issuance of the full power license.

The present authority and procedures in § 50.57(c) of the regulations (under which a presiding ASLB may, on motion, and after a decision based on the evidentiary record or upon agreement of the parties to the contested proceeding, authorize the issuance of a fuel load or low-power and testing license) remain available and are not affected at all by these regulations implementing section 192 of the Act. Thus, temporary operating licensing authority is not coupled to the present § 50.57(c), and a licensee proceeding under § 50.57(c) may also proceed separately under § 50.57(d) without any rights being waived under § 50.57(c). If a licensee already has a low power license and wishes to go to higher or full power using the temporary operating license procedure (that is, it wants to translate its low power authority under § 50.57(c) to low power authority under § 50.57(d) and then to go to higher power under § 50.57(d) for some specified time period), it need simply petition the Commission for an initial temporary operating license. In its petition it should show that it is in satisfactory compliance with § 50.57(d) and that the temporary operating license for low power would be in all respects the same as or more restrictive than the low power license. Although the Commission does not wish to require *pro forma* acts, a licensee in the situation described above should show that the time periods and authorized power level for both types of licenses are compatible. Additionally, if the licensee wishes the Commission to act more quickly and to simplify the Commission's considerations, it may want to show that the parties affected by this situation (ordinarily the parties in the proceeding under § 50.57(c)) have not waived their rights and agree to its proposed course of action; consequently, to make sure that there truly is an agreement and that everyone's rights are being protected, in these circumstances the Commission expects the licensee to demonstrate to it (under the procedures described in § 2.301 *et seq.*, described later) that affected parties were on notice of and have not objected to the licensee's proposed action. The licensee need not make such a showing; however, if it does not wish to or can not make such a showing, though the Commission may still issue the temporary operating license, it may have to use additional procedures to make its decision.

In delineating the circumstances under which petitions may be filed and conditions under which the Commission may exercise its authority, it has carefully followed the prescriptions in section 11 of Pub. L. 97–415. These provisions are reflected in the amendments to Parts 2 and 50. In essence, these amendments would establish a detailed procedural framework for considering and issuing temporary operating licenses. Section 192, as amended, and its accompanying legislative history clearly contemplate that the procedural framework is both useful and needed to govern the

Commission's actions in exercising the new authority and to preserve for the public its right to participate in licensing decisions.

B. Final Subpart C to 10 CFR Part 2—"Procedures Under Section 192 for the Issuance of Temporary Operating Licenses"

Subpart C provides all of the necessary procedural guidance on requests for, and Commission authorization of, temporary operating licenses. Briefly, subpart C provides:

- For the application for a temporary operating license or for an amendment to that license to be filed in the form of a written petition. The written petition with supporting affidavits, must be served on all parties to the proceeding for the issuance of the final operating license.
- The initial petition must be limited to power levels not to exceed 5 percent of rated full thermal power. After the issuance of the temporary operating license, the licensee may file and serve subsequent petitions to amend the temporary operating license by incremental increases in power levels in excess of the initial 5 percent limitation. Each new petition can request only one incremental increase.
- The subpart provides general guidance on the contents and requirements for affidavits which may be filed in support of or in opposition to petitions for the issuance, or the amendment, of temporary operating licenses.
- The Commissioners and their advisors will be able to communicate with the regulatory staff, provided that summaries of such communications, if oral, and copies of such communications, if written, are promptly made available to the parties and the public.
- The final rule provides for prompt publication of notices of petitions for temporary operating licenses as well as for amendments to such licenses and also provides for a 30-day period for public comment for each set of applicant's filings which provides substantive data or argument material to the granting of its application. The notice will inform interested persons about the way they can obtain access to the petition and its supporting affidavits. Such access is needed so that such persons might, as the rules also provide, file and serve responsive affidavits to the petition.
- The final rule does not specify a time after the 30-day public comment period for Commission action on the petition. In keeping with the purpose of the temporary operating license authority, the rule provides that the Commission will act as expeditiously as possible on petitions for temporary operating licenses and for amendments to such licenses.
- Issuance of a temporary operating license or an amendment must be pursuant to a final order of the Commission itself, which recites the reasons called for in section 192 of the Act and in § 50.57(d) of the regulations. As called for by the legislation, the order would be transmitted upon its issuance to the Committees on Interior and Insular Affairs and Energy and Commerce of the House of Representatives and the Committee on Environment and Public Works of the Senate. The final order of the Commission would be subject to judicial review under section 189b. of the Act. As discussed before, pursuant to the legislation, the requirements of section 189a. of the Act would not apply to the issuance or amendment of a temporary operating license. Thus, the legislation authorizes the Commission to use procedures other than formal adjudicatory procedures in issuing a temporary operating license. In this regard, the Commission will develop informal procedures case-by-case to resolve particular issues as they arise.
- The final rule restates the procedural constraints in section 192 to assure that the issuance of a temporary operating license does not prejudge the outcome of the licensing hearing for the final operating license for that nuclear power plant or prejudice the rights of any party to the hearing to raise any proper issue in that hearing and to have that issue decided.
- As discussed above, the rule requires, as does section 192, that any party to the final operating license hearing, or any licensing board member conducting the hearing, promptly notify the Commission about any information made available as part of that hearing: (1) That the terms and conditions of the temporary operating license are not being met or (2) that they are insufficient to provide reasonable assurance that operation of the facility during the period of the temporary operating license will provide adequate protection to the public health and safety and to the environment. The notification must be accompanied by a statement of material facts supporting the assertion, and it must be served on all the parties to the proceedings.
- The rule states that a temporary operating license is subject to modification, suspension or revocation, or to the imposition of civil penalties pursuant to sections 186 and 234 of the Act and subpart B of 10 CFR Part 2.
- Finally, the Commission notes that, pursuant to section 192d. of the Act, it will exert its best efforts to adopt appropriate administrative remedies to minimize the need for the issuance of temporary operating licenses. This is in keeping with the conferees' agreement in the Conference Report that a temporary operating license should be a "last resort remedy, to be employed only when no other alternative is available." Conf. Rep. No. 97–884, 97th Cong., 2d Sess. at 36 (1982). The Commission will also ensure that any administrative remedies it adopts will not themselves infringe upon the right of any party to a full and fair hearing under the Act, again in keeping with the conferees' expectations. *Id.* And, lastly, the Commission will notify the Committees on Interior and Insular Affairs and Energy and Commerce of the House of Representatives and the Committee on Environment and Public Works of the Senate of all administrative remedies it proposes to adopt, also in keeping with the conferees' intentions. *Id.*

C. Final § 50.57(d) of 10 CFR Part 50

Under the final rule, new § 50.57(d) would be added to reflect the substance of the temporary operating licensing authority granted by Pub. L. 97–415 and the special provisions which must be satisfied before the Commission exercises this authority. Pursuant to section 11 of that law and § 50.57(d), the following requirements would be applicable to a petition for and the issuance of a temporary operating license and amendments to that license:

- A petition for the issuance of a temporary operating license could not be filed with the Commission until the Advisory Committee on Reactor Safeguards (ACRS) report, the NRC staff's initial safety evaluation report (SER) and the staff's supplement to this report (SSER) prepared in response to the ACRS report for the plant, the NRC staff's final environmental statement, and, as discussed above, a State, local or utility emergency plan have been filed.
- The initial petition for a temporary operating license and amendments to that license would be handled as described above.
- After the issuance of a temporary operating license, subsequent petitions from the utility for increased power levels, notice and pubic comment periods on each new petition, and the determinations by the Commission called for by section 192 (and implemented in this new § 50.57(d)) would be required before the Commission could allow operation at

power levels beyond the initial 5 percent low-power testing level.

- Before issuing a temporary operating license or amending the license to allow operation at an increased power level, NRC must provide notice of the request for such authority and a 30-day period for public comment.
- Upon the expiration of the 30-day comment period, the Commission could issue the temporary operating license, or amend the license to allow temporary operation at a power level in excess of the initial license limitation, as the case may be, if the Commission itself determined that: (1) All requirements of law, other than the conduct or completion of any required hearing on the final operating license, are met; (2) in accordance with such requirements, there is reasonable assurance that temporary operation of facility, in accordance with the terms and conditions of the license, will provide adequate protection to the public health and safety and the environment; and (3) denial of the temporary operating license will result in delay between the time when the facility is sufficiently completed, in the judgment of the Commission, to permit issuance of the temporary operating license, and the time when a final operating license for the facility would otherwise be issued. For a petition to amend the temporary operating license to permit operation at a power level in excess of 5 percent of the facility's rated full thermal power, the Commission's findings must, of course, be directed to operation at the increased power level which would be authorized by the amendment.
- Any final Commission order authorizing the issuance of a temporary operating license pursuant to section 192 (*i.e.*, as distinguished from an order which may be issued by a presiding ASLB under paragraph (c) of § 50.57) of the Act must recite with specificity the reasons justifying the findings required by that section and § 50.57(d). The order must be sent upon issuance to the Committees described above.
- The temporary operating license would contain such terms and conditions as the Commission may deem necessary, including the duration of the license and any provision for its extension.
- The Commission would suspend the temporary operating license if it finds that the applicant is not prosecuting the application for the final operating license (and on which a hearing under section 189a. is being conducted) with due diligence. The Commission could, of course, suspend the license for other reasons, such as in the interest of public health and safety.
- As discussed above, the Commission also wishes to note that section 192 provides that the Commission's authority to issue new temporary operating licenses will expire on December 31, 1983. Since the Commission cannot issue new temporary operating licenses after December 31, 1983, it expects any licensee that wishes to apply for such a licensee to do so before November 14, 1983, to allow it to act before its authority expires. *See* § 2.301. Licensees should also note that their licenses will not expire on that date; section 192 simply states that the Commission's authority to issue a new temporary operating license will expire on December 31, 1983. It is also clear that the Commission retains its authority to suspend the temporary operating license, if it finds that the applicant is not prosecuting its application for the final operating license with due diligence. *See* § 2.306. Finally, where the Commission has issued a new temporary operating license before December 31, 1983, and, subsequently, the licensee requests an amendment to that license, this provision does not preclude the Commission from amending that license after December 31, 1983.

Paperwork Reduction Act Statement

This rule contains no new or amended requirements for recordkeeping, reporting, plans or procedures, applications or any other type of information collection reviewable by the Office of Management and Budget under the Paperwork Reduction Act.

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this rule does not have a significant economic impact on a substantial number of small entities. This rule affects only the licensing and operation of nuclear power plants. The companies that own these plants do not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the Small Business Size Standards set out in regulations issued by the Small Business Administration at 13 CFR Part 121. Since these companies are dominant in their service areas, this final rule does not fall within the purview of the Act.

Regulatory Analysis

The Commission has prepared a Regulatory Analysis on these amendments, assessing the costs and benefits and resource impacts. It may be found in SECY-83-16, 16A and 16B, and examined at the address indicated above.

Accordingly, pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendments to 10 CFR Parts 2 and 50 are published as a document subject to codification.

List of Subjects

10 CFR Part 2

Administrative practice and procedure, Antitrust, Byproduct material, Classified information, Environmental protection, Nuclear materials, Nuclear power plants and reactors, Penalty, Sex discrimination, Source material, Special nuclear material, Waste treatment and disposal.

10 CFR Part 50

Antitrust, Classified information, Fire prevention, Incorporation by reference, Inter-governmental relations, Nuclear power plants and reactors, Penalty, Radiation protection, Reactor siting criteria, Reporting requirements.

Additional Views of Commissioner Gilinsky

The Commission's decision to apply more relaxed *ex parte* and separation of functions rules to the Temporary Operating License proceeding will very likely raise questions about the Commission's motives and result in more fruitless litigation and delay. The *ex parte* and separation of functions rules should apply uniformly to regular and temporary licenses, especially since similar, and possibly identical, issues are involved.

I agree, however, that the present *ex parte* and separation of functions rules are unduly narrow and should be modified to allow the Commission to communicate directly with the NRC staff and non-parties in licensing cases. To accomplish this, we need to: (1) End the NRC staff's role as a full party in our proceedings; and, (2) make some use of the flexibility afforded to initial licensing by the Administrative Procedures Act. These changes would strike a reasonable balance between the requirements of fairness and the Commission's need to have ready access to information.

Additional Views of Commissioner Asselstine

When this rule was issued in proposed form, I disagreed with the Commission majority's decision not to apply the provisions of 10 CFR 2.719 and 2.780, relating to separation of functions and *ex parte* communications, as part of the procedural requirements for implementing the temporary operating license authority in section 192 of the Atomic Energy Act of 1954, as amended. I

pointed out at the time that in all likelihood, the issues that will be raised before the Commission in the temporary operating license proceeding under the provision of section 192 will be similar to, or the same as, the issues being adjudicated in the hearing in the final operating license proceeding. I therefore concluded that by permitting the NRC staff, the applicant and other parties in the OL proceeding to make informal, off-the-record contacts with the Commission on these issues during the temporary operating licensing (TOL) proceeding, the proposed rule presented the grave risk of contaminating the formal, on-the-record operating license proceeding. For this reason, I recommended applying the Commission's separation of functions and *ex parte* restrictions to the temporary operating license proceeding as well.

After reviewing the comments received on the proposed rule, a majority of the Commission has now agreed to apply the Commission's separation of functions and *ex parte* restrictions to the applicant and intervenors in the TOL proceeding. However, the majority continues to insist upon preserving the opportunity, during the TOL proceeding, to consult privately with the NRC staff on issues that are being contested in the formal operating license proceeding and on which the staff is advocating a position as a part to that proceeding. Even though a written summary of these private contacts would be made, I believe that this approach with respect to the NRC staff has the real potential to create at least the appearance of unfairness in the Commission's role as ultimate judge on the contested issues in the operating license proceeding. This approach will almost certainly lead to challenges to the validity of some Commission decisions in operating license proceedings, thereby providing a new source of uncertainty and unpredictability in our licensing process.

Moreover, I believe that the majority's approach is not necessary to assure that the NRC staff's advice can be made available to the Commission. Even if the Commission's separation of functions and *ex parte* restrictions were to apply to the TOL proceeding, the Commission would be free to consult informally with the staff on general information, on generic issues and on issues that are not being contested in the OL proceeding. In the case of these contested issues, the Commission would be free to hear the advice of the staff in the TOL proceeding as long as the meeting is public, and other parties are notified in advance, are given an opportunity to attend and are given an opportunity to provide their own comments orally or in writing. In my view, these restrictions still permit the Commission to hear from the staff in a manner that will avoid the appearance of unfairness in the Commission's subsequent decision on the contested issues in the operating license proceeding.

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Published 11/17/83
Effective 12/19/83

10 CFR Part 2

Deletion of Exception Filing Requirement for Appeal From Initial Decision; Consolidation of Responsive Briefs

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations relating to appeals from an initial adjudicatory decision. Parties will be required to file a notice of appeal rather than exceptions to the initial decision. In addition, parties will be required to file a single responsive brief, regardless of the number of appellant briefs filed.

This amendment will reduce procedural requirements for appealing an initial decision and permit parties to the proceeding and the agency to focus better their litigative efforts.

EFFECTIVE DATE: December 19, 1983.

FOR FURTHER INFORMATION CONTACT: Trip Rothschild, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone (202) 634–1465.

SUPPLEMENTARY INFORMATION: On June 29, 1983, the Nuclear Regulatory Commission published in the **Federal Register** (48 FR 29876) a notice of proposed rulemaking containing proposed amendments to 10 CFR Part 2. The Commission proposed to eliminate the provision in 10 CFR 2.762 that requires a party appealing an initial decision to file detailed exceptions to the decision with the Atomic Safety and Licensing Appeal Board ("Appeal Board"). Under the current rule each exception must state, without supporting argumentation, the single error of fact or law asserted. Under the proposal, the Commission would require the parties instead to file a notice of appeal which would simply identify the appellant and the decision being appealed.

The Commission noted in the Statement of Considerations that currently, parties who wish to appeal an initial decision must include in their exceptions every possible claim of error to preserve their right to brief the issue. The Commission suggested that this exercise had minimal value because many exceptions are abandonded and not briefed by the appellant. The Commission expressed a concern that the investment of time and effort in the preparation of exceptions, as well as their review by the other parties and the Appeal Board, might be wasted. The Commission stated that its proposal might permit the parties and the agency to focus better their litigative efforts.

The Commission also proposed to limit the number of responsive briefs filed on appeal. In some NRC proceedings there are several appellants. Under current practice respondents may file a separate brief in response to each appellant's brief. The Commission proposed to require each responding party to file a single brief in response to all of the appellants' briefs. The date for filing the responsive brief would run from the date of the last filed appellant's brief. The purpose of this change would be to reduce the amount of paper before the Appeal Board. The Commission noted that it was particularly interested in comments on whether this proposal would preserve an adequate opportunity to respond in cases where there are many issues raised on appeal.

Finally, Commissioner Ahearne (who is no longer a Commissioner) sought comments on whether the rules should be changed to provide that only parties who have filed proposed findings of facts and conclusions of law with an Atomic Safety and Licensing Board ("Licensing Board") on an issue are entitled to appeal an adverse determination.

Summary of Public Comments and Commission Response

The Commission received nine comments. Seven of the commenters represented the nuclear industry; one is an intervenor in NRC proceedings; and the other commenter is a member of the public.

The proposal to eliminate exceptions received mixed reviews. Most commenters had no objection to the consolidation of responsive briefs; virtually all commenters advocated that only parties that had filed proposed findings of fact on an issue should be allowed to appeal a Licensing Board determination.

Elimination of Requirement To File Exceptions

The strongest statement of support for the proposed elimination of the filing of exceptions came from one commenter that asserted that it agreed with the reasoning contained in the Statement of Considerations accompanying the proposed rule. In support of its position, it declared that the Federal Energy Regulatory Commission had adopted many years ago similar appellate procedures which did not call for the filing of exceptions

Some of the commenters expressed reservations about the elimination of the requirement to file exceptions because the current rule requires that appellants specify the precise error of fact or law which they are appealing. In the proposed rule there was no requirement that an appellant in its notice of appeal or in its brief in support of its appeal clearly identify the error of fact or law that is being appealed.

Some commenters who opposed adoption of the proposed rule stated that the filing of exceptions serves useful functions. They argued that the filing of exceptions requires the appellant to focus sharply the issues that will be appealed at the earliest possible time, promptly alerts the other parties to the issues which might be briefed on appeal, and permits the respondents to commence preparation of their responsive briefs at an early date. Some commenters also asserted that, if the problem with the current practice is that exceptions are not prepared in accordance with the NRC Rules of Practice because they fail to identify with requisite specificity the issues to be appealed, the solution is not to eliminate the practice because the review of such pleadings has not been of value to NRC tribunals. Rather, the Appeal Board should refuse to accept inadequate exceptions.

In addition, some commenters did not agree with the Commission's assertion in the Statement of Considerations accompanying the proposed rule that, because parties sometimes request additional time to file an exhaustive list of exceptions, the filing of exceptions delays the appeal process. One commenter thought that the delay caused by the filing of exceptions was minimal. Others thought that if delay were a concern, the preferred solution would be for the Appeal Board to deny requests for an extension of time, absent an extremely strong showing of need.

The Commission has carefully considered these comments and has decided to adopt the proposed rule with minor modifications. The Commission is not convinced that the filing of exceptions serves a useful purpose. The Commission agrees that the Appeal Board could refuse to accept inadequate exceptions. However, the problem is not that the exceptions filed are deficient. Rather, it is that, often, exceptions which are fully adequate under the present rule are, nevertheless, of little use to the Appeal Board or the other parties. Because parties frequently list every conceivable error to preserve their right to brief the issue, many exceptions are later abandoned and never briefed. Accordingly, they do not provide the other parties or the Appeal Board with definitive knowledge of which issues will be briefed. Moreover, the filing of exceptions is not required to apprise the other parties of what the appellant's major concerns are likely to be. Generally after participating in a hearing, the respondents know which are the major issues of concern to the other parties. Thus, the failure to file exceptions should not eliminate a respondent's ability to begin preparation of a responsive filing at an early date. Moreover, the Appeal Panel has concluded that exceptions are not helpful to its review of appeals. Accordingly, on the whole the investment of time and effort in the preparation and review of exceptions is largely wasted. Furthermore, in some cases the appeal process is delayed because extensions are granted to afford parties more time to file detailed exceptions in some of our more complex proceedings. Under the rule we are adopting today, any such delay would be eliminated.

The Commission expects that the elimination of the requirement to file exceptions will also permit the parties and the agency to focus better their litigative efforts. After an initial decision is issued, appellants will be able to devote more time to the preparation of their brief in support of their appeal because it will take far less time, in most cases, to file a notice of appeal than it does to file exceptions. This might improve the quality of briefs.

Therefore, the Commission has concluded that the elimination of the exception filing requirement should enhance both the quality and the efficiency of the appellate process.

In response to the comments the Commission has made one modification to the rule that was proposed. The Commission agrees with the commenters that it is important that the appellant clearly spell out the errors of fact or law so that the other parties and Appeal Board understand the nature of the dispute. In response to this concern, the Commission has revised 10 CFR 2.762(d) to provide that, in its brief, an appellant must clearly specify the errors of fact or law that are being advanced on appeal.

Consolidation of Responsive Briefs

Most of the commenters did not object to the Commission's proposal, although they asserted that in some of the more complex cases, where there are multiple appellants and multiple issues, it might not be feasible for a respondent to include all of its arguments within the seventy page limit for briefs prescribed by 10 CFR 2.762(e). Accordingly, they suggested that the Atomic Safety and Licensing Appeal Board be directed in this Statement of Considerations to grant requests to submit a pleading longer than seventy pages in those proceedings where there are many parties and issues. Other commenters opposed the rule because of a concern that a request to exceed the seventy-page limit might not be granted.

The Chairman of the Commission's Atomic Safety and Licensing Appeal Panel advised the Commission in a letter dated June 30, 1983, which is part of the docket of this proceeding, that in some proceedings the Appeal Board has issued orders limiting a party to one responsive brief and that in those cases the parties did not object. Moreover, the Appeal Panel Chairman assured the Commission that, where appropriate, the Appeal Board would not hesitate to grant requests to exceed the seventy-page limit.

The Commission agrees with the Appeal Panel that limiting a respondent to a single responsive brief would improve the appellate process by reducing the amount of paper before Appeal Boards. The Commission expects Appeal Boards to grant requests to exceed the page limit in cases where there are many parties or issues and where the limit would deprive a respondent of an adequate opportunity to address the issues on appeal.

Several of the commenters suggested that the proposed rule be modified to provide that the respondent's brief be filed no later than 30 days after expiration of the period for filing appellants' briefs.

They noted that one party could file its brief well before the 30-day period for filing briefs closed and that the other parties who filed a notice of appeal might abandon their appeals and not file briefs. The respondent would not know that there was only one brief to respond to until the 30-day period expired. Under the proposed rule, in that situation its response brief would have been due 30 days after the first brief was filed. The respondent would thus find itself in the position of having to respond to the appellant's brief much earlier than anticipated.

The Commission agrees that such a situation would be unfair to the respondent and has modified 10 CFR 2.762(b) to provide that the time for filing respondent's brief is to be calculated from the date that the period for filing briefs expires for all appellants.

Filing of Proposed Findings as a Prerequisite to Filing an Appeal

The proposal that former Commissioner Ahearne sought comment on has also been proposed by NRC's Regulatory Reform Task Force. See SECY-82-447. The Commission is currently considering the proposal in the context of the other reforms proposed by the Task Force, and the comments received will be considered in that context. Accordingly, the Commission has decided to defer any action at this time on the proposal.

However, it should be noted that,

under 10 CFR 2.754 of the Commission's present regulations, when the presiding officer directs that proposed findings be filed, a party may be deemed to be in default and found to have waived its right to appeal on issues on which it fails to file proposed findings.

The Appeal Board has expressed the view that Licensing Boards should routinely direct the parties to file proposed findings. *Detroit Edison Company* (Enrico Fermi Atomic Power Plant, Unit 2), ALAB-709, 17 NRC 17, 24 (1983).

Paperwork Reduction Act Statement

The collection of information these final rules contain is exempt from the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3518(c)(1)).

Regulatory Flexibility Statement

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission hereby certifies that these rules will not have a significant economic impact on a substantial number of small entities. Small entities which appeal initial Commission decisions may experience some cost saving as a result of these rules.

List of Subjects in 10 CFR Part 2

Administrative practice and procedure, Antitrust, Byproduct material, Classified information, Environmental protection, Nuclear materials, Nuclear power plants and reactors, Penalty, Sex discrimination, Source material, Special nuclear material, Waste treatment and disposal.

Under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the following amendments to 10 CFR Part 2 are published as a document subject to codification.

49 FR 8583
Published 3/8/84

10 CFR Part 2

General Statement of Policy and Procedure for Enforcement Actions

AGENCY: Nuclear Regulatory Commission.

ACTION: Revised general statement of policy.

SUMMARY: The NRC is publishing minor revisions to its enforcement policy (47 FR 9987 (March 9, 1982)) based upon its experience to date in implementing the policy. The policy statement is intended to inform licensees and the public of the bases for taking various enforcement actions. The policy is codified as Appendix C to Part 2 of Title 10 of the Code of Federal Regulations. The Commission has also directed that a study of the enforcement program be performed by a small committee of individuals from outside the agency to be selected by the Commission. As a result of this study, additional changes to the policy may be proposed. Comments on these revisions are solicited and will be considered in the in-depth study of the enforcement program.

EFFECTIVE DATE: This revised statement of policy is effective March 8, 1984 while comments on the policy are being received. Submit comments on or before June 1, 1984. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

ADDRESSES: Send comments and suggestions to: Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch. Copies of comments may be examined in the U.S. Nuclear Regulatory Commission Public Document Room, 1717 H Street, NW., Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Jane A. Axelrad, Director, Enforcement Staff, Office of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (301-492-4909).

SUPPLEMENTARY INFORMATION:

Background

The criteria used by the Commission to conduct its enforcement activities were first published on October 17, 1972 (37 FR 21962). These criteria were subsequently modified on January 3, 1975 (40 FR 820) and on December 3, 1979 (44 FR 77135). In late 1979, the Commission directed the staff to prepare a comprehensive statement of enforcement policy. This staff effort was given added urgency by the enactment of Pub. L. 96-295 (signed June 30, 1980), that, among other things, amended Section 234 of the Atomic Energy Act to raise the maximum civil penalty the NRC can impose from $5,000 to $100,000 per violation per day and eliminated the provision limiting the total civil penalties for any 30-day period to $25,000. On September 4, 1980, the Commission approved a proposed general statement of policy on enforcement. Comments were solicited on the policy and a series of public meetings was held. On March 9, 1982, the Commission published a final version of the policy (47 FR 9987).

The policy has now been in effect for about two years. The Commission directed the staff to evaluate the policy and recommend changes if any were necessary. The staff met with groups of utility representatives and public interest groups and consulted the NRC Regional Administrators and Office Directors soliciting comments on whether any changes to the policy should be made. The Commission has determined that, pending further study, no major changes should be made to the policy at this time. The Commission has determined, however, that certain minor revisions should be made now.

The Commission has also directed that an in-depth study of the enforcement program be performed by a small committee of individuals from outside the agency to be selected by the Commission. This study will begin this spring. As a result of this study, additional changes to the policy may be proposed.

The Commission is soliciting comments on the minor revisions described below. These comments will be considered in the in-depth study of the enforcement program. In addition, the Commission is particularly interested in comments on the issue of material false statements. In the VEPCO decision in 1976, Virginia Electric Power Company (North Anna Power Station, Units 1 and 2) CLI-76-22, 4 NRC 480, affirmed, *Virginia Electric & Power Co. v. NRC, 571* F 2d 1289 (4th Cir. 1978), the Commission defined the term "material false statement" as a statement that is false by omission or commission and has the capability to influence a reasonable agency expert. The Commission's staff has been applying this definition and has taken enforcement actions in several cases for violations involving material false statements.

The Commission is interested in comments on the agency's policy on material false statements. Specifically, has the Commission's emphasis on material false statements had a positive effect on the quality of communications with the NRC or has it had a chilling effect on such communications? Should the definition of material false statement be changed to apply only to written statements, submitted under oath? Should materiality be contingent upon the safety significance of the underlying information? Should "materiality" be dependent upon actually influencing an agency reviewer as opposed to having the capability of influencing a reasonable agency reviewer? What would the expected effect of such changes be? As discussed above, these comments will be considered in the in-depth study of the enforcement program and may result in further changes to the policy.

In the following paragraphs, the revisions to the policy which are being made now are described. Only the sections to which changes were made are discussed here. The numbering of the sections tracks the section numbers in the policy.

I. Introduction and Purpose

1. The word "noncompliance" was changed to "violation" wherever it appears in the policy to more precisely describe the focus of the enforcement policy.

2. The phrase "noncompliance should be more expensive than compliance" has been changed to "sanctions should be designed to ensure that a licensee does not deliberately profit from violations of NRC requirements." This change was made to clarify the original intent that licensees committing deliberate violations should receive higher sanctions to remove any benefit attributable to the violation. If this provision were read literally, sanctions for some inadvertent violations of technical specifications would be in the million-dollar range but would not likely prevent future violations. The Commission has concluded that the purpose of the enforcement policy to deter future noncompliance would be better served by reserving such sanctions for deliberate violations of NRC requirements.

II. Statutory Authority and Procedural Framework

The statutory authority section has been revised to note that sections 84 and 147 of the Atomic Energy Act, in addition to the sections already enumerated, authorize the imposition of civil penalties for violations of regulations implementing those provisions.

III. Severity of Violations

1. A few minor editorial changes were made. In addition, changes were made to reflect that a new Supplement, Supplement VIII, was added. This Supplement is discussed in more detail under Supplement VIII.

2. Language has been added to reflect the practice that has been adopted of evaluating some violations in the aggregate and assigning a single severity level for a group of violations. The existing policy provided that to focus on the underlying cause of a violation, the cumulative total civil penalty for all violations that contributed to or were unavoidable consequences of that problem would be based on the amount shown in the civil penalty tables. Since the amount in the tables is based upon the severity level of a violation, the Commission has found it necessary in some cases to aggregate the violations for the assignment of a severity level. In addition, this change is being made to recognize that individual violations, when viewed collectively, may have a greater significance than when considered separately. By aggregating the violations to evaluate the severity level, the Commission hopes to focus attention on the underlying problem or programmatic deficiencies where appropriate.

3. The existing policy indicates that a licensee will be cited for a failure to report a condition or event if it was aware of the condition or event or if enough information existed that the licensee should have been aware of the condition or event. The policy has been clarified to indicate that a licensee will not normally be cited for failure to report a condition or event unless the licensee was actually aware of the condition or event that it failed to report.

4. A clarifying example has been added to the section on willfulness to indicate that inadvertent clerical errors in a document submitted to the NRC is an example of an act that does not rise to the level of careless disregard.

IV. Enforcement Conferences

A new section has been added to the policy containing a description of the circumstances under which enforcement conferences will be held and the information that should be discussed at such conferences. The references in sections IV.B and IV.E to enforcement conferences have been deleted and the substance of these provisions has been included in the new section.

In incorporating the substance of section IV.B, two changes were made. The Commission has noted that enforcement conferences will normally be closed to the public. In addition, the existing policy provided that a civil penalty would not be imposed for a Severity Level IV violation unless a licensee had been cited previously for a similar violation for which an enforcement conference had been held and for which corrective action had proved ineffective. The Commission has, on occasion, wanted to impose a civil penalty for a Severity Level IV violation similar to a previous violation but for which an enforcement conference had not been held. The policy has been changed to delete the reference to a previous similar Severity Level IV violation for which an enforcement conference had been held. Instead, the policy states that the NRC may elect to hold an enforcement conference for Severity Level IV violations which, if repeated, could lead to escalated enforcement action. The policy also states that civil penalties may be imposed for previous similar Severity Level IV violations for which corrective action has proved ineffective in achieving compliance. The NRC will normally hold an enforcement conference before proposing a civil penalty for a Severity Level IV violation.

V. Enforcement Actions

A. Notice of Violation

A few minor editorial changes were made similar to those made in the previous sections. For example, the word "licensee" was changed to "recipient" where appropriate to reflect that under the recent change to 10 CFR 2.200 and 2.201, non-licensees may now be the recipients of Notices of Violation.

B. Civil Penalty

1. The provisions of the policy providing that generally, civil penalties are imposed for Severity Level I and II violations and are considered and usually imposed for Severity Level III violations have been changed. First, the policy has been changed to indicate that mitigation factors may be applied to Severity Level II violations. The purpose of this change is to provide additional incentives to licensees to identify, report, and correct violations. The existing policy that mitigation will not be allowed for Severity Level I violations has not been changed. Second, the policy has been changed to delete the words "usually imposed" for Severity Level III violations. Instead, civil penalties will be considered for these violations. This is consistent with other changes to the policy that are being made to eliminate the many smaller penalties that have been issued to reactor licensees for violations of lesser safety significance.

2. Several changes were made to the factors considered for mitigation or escalation of a penalty.

a. *Prompt identification and reporting*—The reference in this factor, and in the introductory material, to self-disclosing incidents has been deleted. This provision has been difficult to implement, and the Commission has determined that self-identification and reporting should be encouraged to the maximum extent practicable. Therefore, credit of up to 50% will be considered for any violation promptly identified, reported and corrected by a licensee. The amount of credit to be given will be based upon the ease with which it was identified. Thus, less credit will be given for self-disclosing incidents (such as acute overexposures that show up on film badges) than for violations discovered during a licensee audit or surveillance program, but some credit may be given if appropriate.

b. *Corrective action to prevent recurrence*—The policy has been changed to allow for escalation by as much as 50% (instead of the previous 25%) if corrective action is not prompt or if the corrective action is only minimally acceptable. Mitigation of up to 50% will be allowed for unusually prompt and extensive corrective actions. Previously, the policy contained four escalating factors, each allowing for 25% escalation, and two mitigating factors, each allowing for 50% mitigation. However, since the Commission is adding a factor for performance that allows for up to 100% mitigation or escalation, neither the escalation factors nor the mitigation factors will add up to 100%. Instead, the amount of possible escalation will be equal to the amount of possible mitigation for each factor.

c. *Enforcement history*—This factor has been revised to provide for up to 100% mitigation of the base civil penalty for prior good performance in the general area of concern. The policy also provides for up to 100% escalation (increased from 25%) for poor performance in the general area of concern. Under this provision, a civil penalty can be fully mitigated for a first offense in an area of concern or for an offense in an area in which no previous offense had occurred for a period of at least two years. However, a civil penalty can be doubled if a similar violation occurs within a two-year period. It is expected that as a result of this change, fewer small penalties will be issued, particularly for reactors.

In considering prior performance, prior enforcement history, including previous Severity IV and V violations in the area of concern, and escalated enforcement actions will be considered. For reactor licensees, the Systematic Assessment of Licensee Performance (SALP) ratings will also be considered in determining whether mitigation or escalation is appropriate.

d. *Prior Notice of Similar Events*—The only change to this factor was to increase the percentage allowable for escalation from 25% to 50% for the reasons described above.

e. *Multiple Occurrences*—The percentage for escalation in this factor was changed from 25% to 50%. In addition, the qualification on when this factor may be used (when NRC identifies the violation or for violations associated with self-disclosing incidents) has been deleted. The Commission believes that escalation of a penalty may be appropriate where multiple examples of a violation are identified, regardless of who identifies them. However, escalation under this factor may be offset by mitigation for prompt identification and reporting of a violation.

3. Three other changes regarding escalation of penalties have been made. First, consistent with the addition of the factor on past performance, the policy now states that in cases involving willfulness, flagrant NRC-identified violations, repeated poor performance in an area of concern, or serious breakdown in management controls, the NRC intends to apply its full enforcement authority where such action is warranted. Second, a statement has been added to clarify that management involvement in a violation may result in a higher sanction but the lack of such involvement does not mitigate a penalty. This change is being made as a result of the decisions in *Consolidated X-Ray Service Corp.*, ASLBP-83-483-01 OT, 17 NRC 693 (April 28, 1983) and *Atlantic Research*, ALAB-594, 11 NRC 841 (1980) in which an Administrative Law Judge and an Appeal Board, respectively, decided to mitigate two civil penalties because management was not directly involved in the violations. The Commission has determined that mitigation for lack of management involvement could encourage lack of management involvement in licensed activities and might result in a decrease in protection of the public health and safety. The Commission expects management to be closely involved in the control of licensed activities to prevent violations of regulatory requirements. If management causes or condones violations of regulatory requirements, sanctions will be appropriately escalated.

Third, the language on escalation of a penalty for duration and the use of daily civil penalties has been clarified. The policy did not explicitly allow for escalation for duration other than through daily civil penalties. In some cases, it is desirable to escalate a civil penalty for duration without assessing a daily civil penalty. The language has been changed to provide for this.

4. The language regarding Commission approval of issuance of proposed penalties in excess of 3.75 times the maximum civil penalty for a single Severity Level I violation has been moved to the section on Responsibilities (Section VII).

5. The language regarding focusing on the fundamental problems has been clarified as described in Section III above.

6. A number of changes were made to the civil penalty tables:

a. *Safeguards*—Table 1A was revised to establish the same base penalty amount for safeguards violations for reactor licensees regardless of the category of material. This was done because the original designation by IAEA of categories of material was not intended to refer to reactor facilities. The upper limit for the base penalty was selected because the safety consequences of reactor sabotage are considered equal to the safety consequences of theft of material from a Category 1 fuel facility.

b. *Materials Licensees*—The base penalties have been adjusted for some categories of licensees, and base penalties have been added which apply to uranium mills and conversion facilities. These changes were made as a result of experience gained in working with the policy to better equate the amounts of the base civil penalties for various licensees with their health and safety significance.

Table 1A was revised to increase the base civil penalty to $100,000 for Severity Level I violations by power reactor licensees, except for those involving transportation, because the maximum civil penalty is generally appropriate for such violations unless mitigating circumstances are present. This will also result in an increase of the base civil penalties for other severity levels.

C. Esclation of Enforcement Sanctions

Table 2 has been changed to indicate that a civil penalty might not be imposed for the first Severity Level III violation in an area of concern or for an offense in an area in which no previous offense had occurred for a period of at least two years. This change is consistent with the change to the factors allowing complete mitigation for good performance in an area of concern.

D. Related Administrative Actions

The references to enforcement conferences have been deleted and their substance has been covered in section IV. Some minor editorial changes have also been made.

VI. Responsibilities

This section has been changed to reflect the present responsibilities of the Regional Administrators and to reflect existing Commission guidance regarding when Commission consultation is required. In addition to the circumstances previously enumerated in the policy, Commission consultation is now required before issuance of any proposed enforcement action that involves a Severity Level I violation or a material false statement. Commission consultation was required before issuance of a civil penalty involving 3.75 times the Severity Level I values shown in Table 1A. Now, Commission consultation is required prior to issuance of a civil penalty involving 3 times the Severity Level I values shown in Table 1A. For reactor operations, this amount will be $300,000.

VII. The Supplements

The supplements have been changed

in several respects. As described below, a new supplement involving emergency planning has been added. In addition, the introductory language to each of the severity levels in each of the Supplements has been changed to clarify that the examples are only examples and that the examples themselves illustrate the significance of violations of that type. For example, under the old policy, the introductory language for Severity Level I violations under Supplement I contained the words "Very significant violations involving." The revised policy will state "Violations involving for example." The examples provided are examples of violations that the Commission considers to be very significant.

a. *Supplement I.*

1. The policy now includes violations of technical specification limiting conditions for operation (TS LCOs) as Severity Level III violations. However, the examples provided in the policy are confusing. They include TS LCO violations involving a loss of function as examples of both Severity Level II and Severity Level III violations. Furthermore, the TS example for Severity Level III includes a "degraded condition and sufficient information existed to alert the licensee that he was in an action statement condition" which does not take into account the factor that is most often considered in determining the severity level of a TS violation, the safety significance of the system involved in the violation. The Commission is clarifying these examples by deleting the references to loss of function and degraded condition and by providing more explicit examples based upon the safety significance of the violation. The examples provided, two in Severity Level III and two in Severity Level IV, were chosen as fairly obvious examples of significant and less significant TS violations.

2. The word "serious" has been deleted from example 3, Severity Level III, Supplement I because the Commission believes that dereliction of duty itself constitutes a serious violation.

3. The words "when the reported matter does not constitute a violation" have been deleted from Supplement I, Severity Level IV, because these words are unnecessary.

b. *Supplement II.*

No changes were made to Supplement II.

c. *Supplement III.*

The safeguards supplement was revised in three ways.

1. The present examples were clarified to indicate that it is the loss of one or more of the elements of access control that determines the severity level of a violation.

2. New examples were added to distinguish violations relating to the protection of safeguards information of lesser significance from those that involve information which would significantly assist an individual in an act of radiological sabotage or theft of special nuclear material.

3. The failure to perform a proper search at an access control point that results in the introduction of contraband to the site was added as a Severity Level III violation. Some violations of search requirements may be considered minor. However, the search procedure is expected to uncover attempts to introduce contraband to the site and, when this failure is demonstrated by the actual introduction of contraband, it is clearly a significant violation.

d. *Supplement IV*—Minor changes were made to this supplement. A change was made to one example of a Severity Level III violation to bring the example into closer conformance with the relative significance of similar examples under other severity levels for this supplement.

e. *Supplement V*—Minor changes were made to this supplement to ensure that a graduated approach to violations was adequately described in the examples.

f. *Supplement VI*—Minor changes were made to this supplement.

g. *Supplement VII.*

1. Examples were added to this supplement to address the Commission's increasing concern with violations involving falsification of records. The Commission views falsification of records which the NRC requires be kept to be a serious concern. The records are required to be kept to enable a licensee to adequately control the safety of its licensed activities. In addition, deliberate falsification of records of significant information by management personnel is obviously a serious violation. Accordingly, violations involving deliberate falsification of significant records by or with the knowledge of management are considered Severity Level I violations. Either deliberate falsification, or falsification by or with the knowledge of management, of significant records is described as an example of a Severity Level II violation. Any other falsification of significant records is described as an example of a Severity Level III violation.

2. The examples for violations involving discrimination against an employee in violation of Section 210 of the ERA have been clarified. Violations by senior corporate management have been categorized as Severity Level I violations. Violations by plant management above first-line supervision have been categorized as Severity Level II violations, and violations by first-line supervision have been categorized as Severity Level III violations.

3. The examples regarding Part 21 violations have been made consistent with statutory authority.

h. *Supplement VIII—Emergency Preparedness.*

The existing Enforcement Policy did not contain any examples of emergency preparedness violations in any of the supplements. However, the Commission has been taking enforcement actions under the emergency preparedness rules and guidance is necessary regarding what enforcement actions are appropriate. Accordingly, the Commission has developed a new Supplement VIII on Emergency Preparedness containing examples of emergency preparedness violations of varying severity. The examples are based upon the planning standards in 10 CFR 50.47(b). Since the planning standards on assessment and notification are considered to be the most significant, violations of more than one of these standards is considered a Severity Level II violation. No examples of Severity Level I violations of planning standards are provided because the Commission did not believe that violations of these standards should be considered as significant as a failure to classify, notify, or respond to an event in a general emergency, the example provided of a Severity Level I violation. The other examples are based upon failure to promptly classify, notify, or respond to an event, and are distinguished by the emergency action level that best describes the event. By "correctly classify," the Commission means classify at a sufficiently high protective action level. Enforcement action will not normally be taken for overclassifying an event.

List of Subjects in 10 CFR Part 2

Administrative practice and procedure, Antitrust, Byproduct material, Classified information, Environmental protection, Nuclear materials, Nuclear power plants and reactors, Penalty, Sex discrimination, Source material, Special nuclear material, Waste treatment and disposal.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and Section 552 of Title 5 of the United States Code, the following statement of policy is published as Appendix C to 10 CFR Part 2 as a document subject to codification to be effective immediately.

49 FR 9352
Published 3/12/84
Effective: Upon approval of OMB or 6/7/84.

Environmental Protection Regulations for Domestic Lincensing and Related Regulatory Functions and Related Conforming Amendments

See Part 51 Statements of Consideration

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49 FR 24110
Published 6/12/84
Effective: 6/12/84

10 CFR Part 2

Abolition of the Position of Appeal Panel Vice Chairman

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations to abolish the position of permanent Vice Chairman of the Atomic Safety and Licensing Appeal Panel and to authorize the most senior available full-time Appeal Panel member to perform certain functions previously performed by the Vice Chairman. Specifically, these amendments will authorize such Appeal Panel member to assign members of the Panel to serve as members of an Atomic Safety and Licensing Appeal Board for a particular proceeding if the permanent Chairman of the Panel is not available to make the assignment. The amendments will also authorize the most senior available full-time Appeal Panel member to act for an Appeal Board on procedural matters in specified circumstances.

EFFECTIVE DATE: June 12, 1984.

FOR FURTHER INFORMATION CONTACT: Linda S. Gilbert, Office of the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Telephone: (301) 492–7678.

SUPPLEMENTARY INFORMATION: Under § 2.787 of the Commission's rules of practice, the permanent Vice Chairman of the Atomic Safety and Licensing Appeal Panel is assigned certain administrative and procedural duties in specified circumstances. The Commission has decided to abolish the position of permanent Vice Chairman of the Appeal Panel. In connection with this action, the Commission is amending § 2.787 to authorize the most senior available full-time Appeal Panel member, based on the date of appointment as a member of the Panel, to perform those functions previously performed by the Vice Chairman under that section.

Section 2.787(a) governs the assignment of Appeal Panel members to serve on three-member Appeal Boards for particular proceedings. Among other things, it provides that the permanent Chairman of the Appeal Panel shall make such assignments. In the absence of the Chairman, the permanent Vice Chairman of the Appeal Panel shall perform this function. The section has been amended to provide that, in the absence of the Chairman, the most senior available full-time member of the Appeal Panel shall assign Panel members to serve on particular Appeal Boards.

Section 2.787(b) sets forth the persons who are authorized to act for an Appeal Board on procedural matters, including requests for stays of orders of presiding officers, in the absence of a quorum. They are, in order of preference: (1) the Chairman of the Appeal Board assigned for the particular proceeding, (2) the permanent Chairman of the Appeal Panel, or (3) the permanent Vice Chairman of the Appeal Panel. Section 2.787(b)(3) has been amended to substitute the most senior available full-time Appeal Panel member for the permanent Vice Chairman of the Appeal Panel.

The language of § 2.787(b)(3) has also been revised to clarify when the most senior available full-time Appeal Panel member is authorized to act for an Appeal Board on procedural matters. Specifically, the following two conditions must be met: (1) the Chairman of the particular Appeal Board must be unavailable or the position must not yet be assigned, and (2) the permanent Chairman of the Appeal Panel must be unavailable or the position must be vacant.

These amendments relate solely to minor matters of agency management and do not themselves alter the rights or interests of parties or licensees. Accordingly, the notice and comment procedures of the Administrative Procedure Act, 5 U.S.C. 553, are inapplicable and the amendments may be made effective on publication in the **Federal Register**.

Paperwork Reduction Act Statement

The information collection requirements contained in this final rule are exempt from the Paperwork Reduction Act of 1980 (44 U.S.C. 3518(c)(1)).

List of Subjects in 10 CFR Part 2

Administrative practice and procedure, Antitrust, Byproduct material, Classified information, Environmental protection, Nuclear materials, Nuclear power plants and reactors, Penalty, Sex discrimination, Source material, Special nuclear material, Waste treatment and disposal.

The authority citation for this document is:

(Sec. 161, Pub. L. 83–703, 68 Stat. 948, as amended (42 U.S.C. 2201))

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended and 5 U.S.C. 552, 553, the NRC is adopting the following amendments to 10 CFR Part 2.

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49 FR 24512
Published 6/14/84
Effective 6/7/84

10 CFR Parts 2, 30, 40, 50, 51, 61, 70, 72, and 110

Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions and Related Conforming Amendments

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule and confirmation of effective date.

SUMMARY: In a final rule published in the **Federal Register** on March 12, 1984 (49 FR 9352), the Nuclear Regulatory Commission revised its regulations to implement section 102(2) of the National Environmental Policy Act of 1969 (NEPA), as amended, consistent with NRC's domestic licensing and related regulatory authority. This notice amends this final rule to include the approval of its collection of information requirements that were approved by the Office of Management and Budget on June 6, 1984, and to confirm the effective date of the final rule as June 7, 1984. This notice also removes the section, published May 9, 1984 (49 FR 19627), that set out information collection requirements approved by OMB as of December 31, 1983, because this section has been superseded by the revision to Part 51 and OMB approval of the information collection requirements contained in that revision.

EFFECTIVE DATE: June 7, 1984.

FOR FURTHER INFORMATION CONTACT: Jane R. Mapes, Senior Regulations Attorney, Regulations Division, Office of the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Telephone: 301–492–8695.

SUPPLEMENTARY INFORMATION: The collection of information requirements in this final rule were not approved by the Office of Management and Budget (OMB) at the proposed rule stage because the proposed rule was published prior to April 1, 1981, when the Paperwork Reduction Act became effective.

List of Subjects in 10 CFR Part 51

Administrative practice and procedure, Environmental impact statements, Nuclear materials, Reporting and recordkeeping requirements.

➢ 49 FR 35747
Published 9/12/84
Effective 10/12/84 (49 FR 36631)

10 CFR Parts 2 and 50

Elimination of Review of Financial Qualifications of Electric Utilities in Operating License Review and Hearings for Nuclear Power Plants

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: In response to a remand by the U.S. Court of Appeals for the D.C. Circuit which declared invalid the Commission's March 31, 1982 rule eliminating financial qualification review and findings for electric utilities at all stages of the licensing proceeding, the Nuclear Regulatory Commission (NRC or Commission) is amending its regulations to eliminate financial qualification review and findings for electric utilities that are applying for operating licenses for utilization facilities if the utility is a regulated public utility or is authorized to set its own rates. The Commission is reinstating a requirement for financial qualification review and findings for electric utilities that are applying for construction permits.

➢ **EFFECTIVE DATE:** October 12, 1984.

FOR FURTHER INFORMATION CONTACT: Carole F. Kagan, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC. 20555, Telephone: (202) 634-1493.

SUPPLEMENTARY INFORMATION:

I. Background

On April 2, 1984, the Commission published in the Federal Register (49 FR 13044) a notice of proposed rulemaking which would eliminate financial qualification review and findings for electric utilities applying for operating licenses for utilization facilities if the utility is a regulated public utility or is authorized to set its own rates. As detailed in the notice of proposed rulemaking, this action was taken in response to the decision of the District of Columbia Court of Appeals in *New England Coalition on Nuclear Pollution* v. *NRC*, 727 F.2d 1127 (D.C. Cir. 1984) which remanded the Commission's March 1982 rule (47 FR 13750) eliminating financial qualification review and findings for electric utilities applying for facility construction permits and operating licenses. The Court found the Commission's explanation of the final rule internally inconsistent because, in the Court's view, the reasons the Commission advanced for dispensing with the financial qualification review for electric utilities would, if supported by the facts, apply generally to all license applicants and would not support a rule that singled out utilities for special treatment.[1]

The proposed rule on remand was promulgated on the Commission's belief that case-by-case review of financial qualifications for all electric utilities at the operating license stage is unnecessary due to the ability of such utilities to recover, to a sufficient degree, all or a portion of the costs of construction and sufficient costs of safe operation through the ratemaking process. It is well established that public utility commissions (PUCs) are legally bound to set a utility's rates such that all reasonable costs of serving the public are recovered, assuming prudent management of the utility. *See, e.g., Federal Power Commission* v. *Hope Natural Gas Company*, 320 U.S. 519 (1944); *Bluefield Water Works and Improvement Company* v. *Public Service Commission of the State of West Virginia*, 262 U.S. 679 (1923). The Commission is reinstating financial qualification review for all construction permit applicants for the reasons stated in the notice of proposed rulemaking. (49 FR 13045).

The notice of proposed rulemaking solicited comments from interested persons. In order to provide additional information for the Commission's consideration in this rulemaking, NRC staff members visited with senior staff members of seven public utility commissions, two Federal agencies that regulate nuclear utilities and three publicly-owned[2] nuclear utilities. Telephone inteviews were conducted with two other State public utility commissions (New York and California) in response to concerns raised by commenters on the proposed rule. In addition, the staff analyzed data submitted by the National Association of Regulatory Utility Commissioners (NARUC) from its recent national survey of its member State public utility commissions and of publicly-owned nuclear utilities. This survey, referenced in the Notice of Proposed Rulemaking, was designed to determine whether, historically, utilities which have requested rate increases or rate provisions for operating safety requirements have regularly received them.

II. Analysis of Public Comment

A. Public Comment on the Proposed Rule

Forty-two comments were received on the proposed rulemaking. Slightly more than half of the commenters favored the proposed rule. Nearly all of these specifically endorsed the agency's conclusion that the regulated nature of public utilities assures adequate funding for safe operation through the ratemaking process. Most of these also indicated support for complete elimination of the financial qualification review requirement at all stages of the licensing process on the ground that there is no proven link between financial qualification reviews and safety. Two commenters espoused the view that Section 182 of the Atomic Energy Act does not mandate such reviews.

Several commenters expressed the view that the NRC's inspection and enforcement program is a more direct and efficient way of assuring operating safety than a review of a utility's finances. In addition, it was argued that the PUCs can more efficiently monitor the financial health of a utility on a continuing basis than can the NRC, whose expertise is in the health and safety area. The Commission, two commenters pointed out, can only judge the financial health of a utility based on prediction, while it can provide continual monitoring on health and safety issues.

Commenters opposing the proposed rule raised a number of issues. In the main, they disputed the premise that the ratemaking process provides reasonable assurance that utilities will be able to recover sufficient funds to safely operate a facility. Several grounds were offered for this attack:

- A utility may not achieve an expected rate of return (i.e., profit) from the ratemaking process.
- Utilities may not recover every cost item requested from the PUCs.
- Portions of new plants are sometimes phased into the rate base over a period of time, so the utility will not immediately recover all necessary expenses.
- Costs may be disallowed if imprudently incurred.
- Some States are preempted by the NRC's licensing authority from judging the financial capabilities of the utilities they regulate.
- Publicly-owned utilities are not assured of funding through the ratemaking process.

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[1] In view of the limited applicability of the rationale expressed in the proposed rule and in this final rule, the concerns expressed by the Court no longer apply.

[2] "Publicly-owned utilities" are utilities owned by governmental units, governmentally-chartered units such as public utility districts, or by groups of consumers such as rural cooperatives, including associations of any of the foregoing.

Other objections raised by commenters to the proposed rule were that review at the construction permit stage only comes too early to judge the actual capability of a utility to finance a nuclear facility; that there is no assurance that utilities will apply monies obtained through the ratemaking process to operating plants, rather than to facilities under construction, and that utilities have an incentive to put plants on line too early in order to obtain rate base treatment.

The Commission believes that many of the concerns expressed about the proposed rule reflect a misunderstanding of the nature of the Commission's jurisdiction over, and prior reviews of, the financial qualifications of utility applicants. The original rule requiring financial qualification review, promulgated in 1968, required a finding, prior to operating license issuance, that the utility "possesses or has reasonable assurance of obtaining the funds necessary to cover the estimated costs of operation for the period of the license or for five years, whichever is greater, plus the estimated costs of permanently shutting the facility down and maintaining it in a safe condition." As can be seen, the focus of the rule was on the availability of funds, rather than on whether funds were properly spent.

Despite the longstanding nature of the financial qualification reviews under the original rule, their safety rationale seems never to have been clearly set out. A financial disability is not a safety hazard *per se* because the licensee can, and under the Commission's regulations would be obliged to, simply cease operations if necessary funds to operate safely were not available. At most, the Atomic Energy Commission, in drafting the rule, must have intuitively concluded that a licensee in financially straitened circumstances would be under more pressure to commit safety violations or take safety "shortcuts" than one in good financial shape. Accordingly, the drafters of the rule sought to achieve some level of assurance, prior to licensing, that licensees would not be forced by financial circumstances to choose between shutting down or taking shortcuts while the license was in effect.

The limited scope of this approach as it bears on safety is apparent. Having a reasonably assured source of funds does not assure that money intended or allocated for safety reasons will be so spent. Moreover, concerns regarding safety performance are not confined to those utilities with financial difficulties. A whole host of circumstances, including poor training, inattention to detail, poor management attitude, and lack of safety commitment, can conceivably lead to poor safety performace. Many of these other concerns are subsumed within the topic "managment integrity," which has been a focus of several pending licensing proceedings.

Given the inherent limitations of the rule, it must have been the rule drafters' intent that the question of potential misuse of available funds, like these other integrity concerns, be addressed elsewhere, either in the review of the applicant's technical qualifications, managment, and training prior to licensing, or by the Commission's post-licensing inspection and enforcement process.

This is confirmed by longstading practice under the original rule. Prelicensing financial reviews under the rule were, as the rule itself suggests, confined to assuring a source of funds, and no effort was made at that stage to establish assurance that funds would be properly spent. Thus the concerns expressed by some commenters that the ratemaking bodies do not assure that funds received by a utility through the ratemaking process will actually be applied to meeting the requirements for safe operation are not relevant to consideration of the Commission's financial qualification rule. Even though the rate process does no more than assure that regulated utilities will have the financial resources needed to operate safely, this limited assurance is all that the financial qualification rule was intended to achieve. These commenters' concerns go not to the need to reinstate financial qualification reviews, but to other issues beyond the scope of this rulemaking that have been, and continue to be, addressed in prelicensing review of applicant's technical qualifications, managment and training, and by the post-licensing inspection and enforcement process.

A second misunderstanding stems from the impression that a utility would have to be guaranteed a rate of recovery equal to every penny it requested from the rate commission in order to assure safe operation. This impression has led several commenters to object to the proposed rule on the basis that rate regulation does not ensure a fixed level of profitability.

Neither in this rule nor in its financial qualification review has the Commission made any assumption as to the rate of return or the level of profit to be allowed to utilities from the operation of nuclear plants. Its concern is that reasonable and prudent costs of safely maintaining and operating nuclear plants will be allowed to be recovered through rates. This concern does not extend to any level of profit or rate of return beyond those operating expenses. The Commission's concern is with safe operation, not profits.

The same misunderstanding underlies the comment that utilities do not recover every cost item requested from rate commissions. It is not uncommon for a rate commission to deny certain requested cost items or portions thereof. These disallowances, however, deny a utility only a small portion of its total revenues. The amount of the disallowance may be reflected in a smaller profit margin, but the costs denied by the ratemaking bodies are not so great that the amount of these disallowances would exceed operating costs. NRC conversations with ratemaking bodies as well as the results of the NARUC questionnaire confirm that it is standard practice among ratemaking bodies to factor in the amount of disallowances to ensure that utilities receive enough rate relief when a plant goes into operation to recover all resonable costs of safe operation.

The same reasoning applies to the comment that rate base phase-ins and disallowances (portion of new plants either not allowed into the rate base or phased in to the rate base over a period of time) affect the utility's recovery of operating expenses. Again, such phase-ins may affect short-term profits, but does not affect recovery of operating expenses.

No sound basis has been shown for the allegation raised by the State of Texas that a State may be preempted from judging the financial capabilities of the utilities it regulates, because only the NRC has the authority to issue licenses and order shutdowns, or for the allegation that publicly-owned utilities are not assured of funding through the ratemaking process. The NRC's analysis of the NARUC survey, discussed *infra*, has shown that all State public utility commissions have sufficient ratemaking authority to ensure sufficient utility revenues to meet the cost of NRC safety requirements. Similarly, it has been shown that publicly-owned utilities have independent rate-setting authority which is used to cover the costs of operation, including those of meeting NRC safety requirements.

B. Public Comments on the NARUC Study

As indicated above, the National Association of Regulatory Utility Commissioners (NARUC) submitted to the Commission the results of a national survey of its members regarding the provision for nuclear plant operating funds through a State commission's ratemaking process. The survey also included the Federal Energy Regulatory Commission and a broad sample of publicly-owned nuclear utilities. The NRC staff analyzed the survey, and the results of both the survey and the NRC's analysis were placed in the NRC Public Document Room. An extension of the comment period on the rule was provided in order to give the public an opportunity to comment both on the survey and on the NRC analysis.

The NRC staff found that the survey lends strong support to the proposed rule. The conclusion that emerged from the study was that ratemaking authorities had varying mechanisms to ensure sufficient utility revenues to meet the costs of NRC safety requirements, but that all had such mechanisms. Only one instance was identified (Arkansas) where a revenue request to enable a utility to meet what were purported to be nuclear safety costs was denied.[3] That case is currently on appeal. Most ratemaking bodies indicated that no specific provision was made for NRC safety requirements, but that rates are established in general rate cases to produce sufficient overall revenues to assure sound functioning of the electric power systems, including nuclear plants. Some PUCs did indicate that their orders specifically allocate funds to meet NRC safety requirements. This question was a subject of particular focus during NRC staff visits to PUCs. The PUCs visited were unanimous in saying that safety-related operating expenses were *always* considered reasonable expenses when prudently incurred and were allowed to be recovered through rates.

Publicly-owned nuclear utilities were also surveyed. It was found that these have independent rate-setting authority that is used to recover costs of operation, including the costs of meeting NRC safety requirements. Exceptions were two cooperative utilities that, by State law, have their rates regulated by the State public utility commissions. Many publicly-owned and investor-owned nuclear plants are owned by groups of utilities, rather than solely-owned. Where this is the case, the respondents to the NARUC study indicated that they have contractual agreements with the other co-owners to increase their contributions to operating costs if total costs increase over time. The amount of any such increase is proportional to each utility's relative ownership share in the plant.

Those commenters who endorsed the Commission's conclusions on the NARUC study did so on the basis that the study shows that, no matter the regulatory mechanism, all PUCs and publicly-owned utilities have the authority to set rates in such a way that sufficient revenues to meet NRC safety requirements are assured.

One commenter stated that in one-quarter of the States regulators do not have the authority to assure adequate revenues to cover nuclear safety costs. This is incorrect. In those States, regulators do not have *specific* authority to treat nuclear safety costs as a separate case. They do, however, have a general grant of authority to allow recovery of all reasonable costs through rates. As previously indicated, reasonable costs of meeting NRC requirements are virtually automatically included within that definition.

The same commenter raised several objections to the conclusions drawn from the NARUC survey by the NRC. That commenter's primary argument is that the purpose of State utility regulation is not to assure the financial health of public utilities or to assure that utilities request funds for and devote funds to assure nuclear safety. The Commission understands the commenters's concern to be that State regulation will not assure the utility sufficient profits to allow it to safely operate a facility. This concern is unfounded. While the purpose of State utility regulations is not to assure profits, it is to set rates at such a level that the public is assured an adequate supply of power at the fairest possible price. In order to attain this goal, it is essential that the utility have the opportunity to earn a reasonable amount of profit. A financially unsound utility will not serve the goals of either the rate-regulating body or the public.

The Commission has never asserted that rate regulators assure that utilities devote a specific portion of their funds to nuclear safety. The commenter apparently believes that the NRC's past financial reviews monitored nuclear power plant expenditures to see where the funds went. As explained above, this has never been the case. The Commission examined a utility before a license was granted to assure that, in the Commission's judgment, the utility had sufficient *total* revenues to operate a facility. The Commission did not examine the books of facilities to assure that monies requested for safety expenditures were so spent, but relied on its inspection and enforcement program to ensure that each facility met all NRC safety regulations. This will remain unchanged under the present rule.

The Commission believes that the record of this rulemaking demonstrates generically that the rate process assures that funds needed for safe operation will be made available to regulated electric utilities. Since obtaining such assurance was the sole objective of the financial qualification rule the Commission concludes that, other than in exceptional cases, no case-by-case litigation of the financial qualification of such applicants is warranted. Some of the other concerns expressed by commenters, including concerns that available funds will not be spent properly for safety matters, will continue to be separately addressed by the Commission, either in pre-licensing reviews or in the post-licensing inspection and enforcement program.

C. Public Comment on the Link Between Financial Qualification Review and Assurance of Safety

The Commission also sought comment on the question of whether financial qualification reviews could be eliminated completely at both the construction permit and operating license stages on the basis that there is no connection between these reviews and health and safety. Nearly all commenters who wrote in support of the proposed rule also indicated that they would support such a proposal. The commenters relied on the fact that no correlation has been shown between financial qualification and safety, that the Commission's financial reviews are essentially predictive and cannot adequately anticipate what the actual costs of operation will be, that financial incentives do not favor reducing the operating and maintenance costs associated with nuclear power reactors, that the consequences of a serious incident at a nuclear power plant would be too severe to warrant cutting corners on safety, that the financial condition of a utility improves once a facility is operating and that the NRC's inspection and enforcement program is a more efficient method of insuring safety. One commenter[4] enclosed a May 31, 1984 report from National Economic Research Associates, Inc. (NERA) which studied investor-owned utilities and concluded that an examination of the financial condition of electric utilities at the operating license stage is unlikely to produce any useful insight into the safe operation of nuclear power reactors. NERA based its conclusions upon an analysis of the financial incentives associated with operating nuclear power reactors, the relationship between nuclear-related operation and maintenance costs and measures of utility financial health, and general considerations of what happens to the financial condition of electric utilities when a new reactor begins operation. NERA concluded that incentives to cut costs and increase profits by cutting corners are outweighed by the financial risks of cutting corners, that there is a greater chance of shutdown and removal from the rate base in case of accident in a nuclear facility, and that it is easier for a utility that operates both nuclear and non-nuclear facilities to reduce non-nuclear rather than nuclear costs.

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[3] In that situation, the dispute revolved around a single facility which was to serve both as a visitor's center (non-safety-related expense) and as an emergency response center (safety-related expense). The issue was which portion of the costs of that facility should be defined as safety-related and, therefore, recoverable through rates.

[4] This commenter also suggested that, if the Commission were to reinstate financial qualification review for construction permit applicants, it should also reinstate that portion of Appendix C to 10 CFR Part 50 which provides guidance for such review. The Commission has done so in this final rule.

Most commenters who opposed the Commission's rule chose not to comment separately on this issue. Those that did cited the allegedly poor financial health of some utilities, but failed to identify any link between the NRC's financial qualification reviews and the safe operation of facilities owned by these utilities.[8]

≫ The NRC has found some indication in the public comments, and especially in the NERA report, that a rule eliminating financial qualification review at all stages of the licensing proceeding is supportable, at least for regulated utilities, on the basis of the lack of any proven link between financial qualification review and safety given the Commission's long experience in regulating utilities, the data in the NERA report, and the further public comment. Since the Commission has had less experience with and less information on the subject of non-utility licensees, and since the Commission has indicated that it would not issue a final rule on this basis without a further opportunity for public comment, the Commission is not relying on this premise for the current rule. The Commission does, however, note that there is some support for the proposition that, for electric utilities, there is no connection between the Commission's financial qualification review and safe operation of a facility.

III. Additional Information That Can Be Required

By this rule, the Commission does not intend to waive or relinquish its residual authority under Section 182a of the Atomic Energy Act of 1954, as amended, to require such additional information in individual cases as may be necessary for the Commission to determine whether an application should be granted or denied or whether a license should be modified or revoked. An exception to or waiver from the rule precluding consideration of financial qualification in an operating license proceeding will be made if, pursuant to 10 CFR 2.758, special circumstances are shown. For example, such an exception to permit financial qualification review for an operating license applicant might be appropriate where a threshold showing is made that, in a particular case, the local public utility commission will not allow the total cost of operating the facility to be recovered through rates.

IV. Practical Impacts

The rule will, in normal circumstances, reduce the time and effort which the applicants, licensees, the NRC staff and NRC adjudicatory boards devote to reviewing the applicant's or licensee's financial qualifications in comparison to the rule which existed before March 31, 1982. The rule eliminates staff review at the operating license stage in cases where the applicant is an electric utility presumed to be able to finance activities to be authorized under the license. The rule will be applied both to ongoing and future licensing reviews and proceedings and to past proceedings subject to the remanded rule. The rationale for the rule is in effect a generic determination that regulated or self-regulating public utilities are financially qualified to operate nuclear power plants. Accordingly, this rule amounts to a generic resolution of financial qualification issues that may be pending in operating license proceedings involving electric utilities. The NRC neither intends nor expects that the rule will affect the scope of any issues or contentions related to a cost/benefit analysis performed pursuant to the National Environmental Policy Act of 1969. Under NEPA, the issue is not whether the applicant can demonstrate reasonable assurance of covering certain projected costs, but what costs to the applicant of constructing and operating the plant are to be put into the cost-benefit balance. As is now the case, the rule of reason will continue to govern the scope of what costs are to be included in the balance, and the resulting determinations may still be the subject of litigation.

Paperwork Reduction Act Statement

This rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). These requirements were approved by the Office of Management and Budget, OMB Approval No. 3150–0011.

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the NRC hereby certifies that this rule will not have a significant economic impact on a substantial number of small entities. The rule reduces certain minor information collection requirements on the owners and operators of nuclear power plants licensed pursuant to sections 103 and 104b of the Atomic Energy Act of 1954, as amended, 42 U.S.C. 2133, 2134b. These electric utility companies are dominant in their service areas. Accordingly, the companies that own and operate nuclear power plants are not within the definition of the Small Business Act, 15 U.S.C. 632, or within the Small Business Size Standards set forth in 13 CFR Part 121.

List of Subjects

10 CFR Part 2

Administrative practice and procedure, Classified information, Confidential information, Freedom of information, Hazardous materials, Nuclear materials, Nuclear power plants and reactors, Penalties, Sex discrimination.

10 CFR Part 50

Administrative practice and procedure, Antitrust, Fire prevention, Classified information, Intergovernmental relations, Nuclear power plants and reactors, Radiation protection, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and section 553 of Title 5 of the United States Code, the NRC is adopting the following amendments to 10 CFR Parts 2 and 50.

Additional Views of Commissioner Asselstine

A majority of the Commission has concluded that in its consideration of an application for an operating license for a nuclear power plant, no review whatsoever of the utility applicant's financial qualifications to operate the facility is required and, other than in exceptional cases, no case-by-case litigation of the financial qualification of the applicant is warranted. The majority's conclusion appears to be based upon the judgment that the record of this rulemaking demonstrates generically that the rate process assures that funds needed for safe plant operation will be made available to regulated electric utilities.

Although the NRC should not return to performing the same types of financial qualification reviews required by the old rule, the majority has gone too far in excluding virtually all consideration of the utility applicant's financial qualification in nuclear power plant operating license proceedings. Such a sweeping exclusion is contrary to the requirements of the Atomic Energy Act, is unsupported by the facts and is unjustified on the basis of this rulemaking record.

Section 182 a. of the Atomic Energy Act of 1954 requires that each application for an operating license for a nuclear power plant "specifically state such information as the Commission, by rule or regulation, may determine to be necessary to decide such of the technical and financial qualifications of the applicant . . . as the Commission may deem appropriate for the license." The plain language of the statute appears to require consideration of the financial qualification of the applicant as part of the Commission's decision on whether to issue an operating license for a nuclear power plant. Thus, at least absent clear and convincing evidence that the financial qualification of a regulated utility is wholly irrelevant to safe plant operation in all cases (evidence that is not to be found in this rulemaking record), the Commission is required to perform some type of financial qualification review and to consider financial qualification issues as part of the licensing proceeding for a nuclear power plant.

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[8] It is important to note that, if such a link could be identified for any given facility, the Commission would not be precluded from examining the financial qualification of that facility under 10 CFR 2.758. *See* Section IV, *infra.*

The majority points to a survey conducted by the National Association of Regulatory Utility Commissions (NARUC) which shows that public utility commissioners and publicly-owned utilities have the authority to set rates in such a way that sufficient revenues to meet NRC safety requirements are assured. However, the fact that regulated electric utilities can generally expect to be compensated for the cost of safety requirements does not provide a basis for eliminating all consideration of financial qualification issues in operating license proceedings.

As the NARUC study itself confirms, public utility commissions typically do not specify that funds to cover safety requirements must be spent on nuclear plant operations. Nor are nuclear plant operating costs the only element considered by public utility commissions in deciding on the amount of revenues to be provided to the utility. As some commenters noted, utility rate commission decisions can include elements such as rate base phase-ins or disallowances that affect the overall rate level allowed for the utility. Such factors, together with the cost of ongoing construction programs that frequently are not included in the rate base, inevitably require the utility to make choices regarding the allocation of rate returns among such competing priorities as nuclear and non-nuclear plant operating costs, plant improvements aimed at increasing plant capacity factors, increasingly costly construction programs and providing an adequate rate of return to investors. The difficult financial choices faced by some utilities, particularly smaller utilities with larger ongoing construction programs, are widely documented. There is simply no basis in this rulemaking record for concluding that in all instances a utility will resolve the conflicting financial priorities in favor of allocating full funding to nuclear plant operation. In the absence of such evidence, the fact that utility commissions typically provide rate relief sufficient to cover the cost of safety requirements does not, by itself, justify the total exclusion of all financial qualification issues and the elimination of all financial qualification reviews.

The majority also argues its conclusion is supported by the agency's long experience in regulating utilities, and that present inspection and enforcement efforts are a sufficient means for identifying and correcting financially motivated safety problems. The majority, although professing not to rely on this point, further attempts to bolster its position by asserting that there is some support for the proposition that there is no link between financial qualification reviews and safety. In support of this assertion, the majority points to a study by the National Economic Research Associates, Inc. (NERA), which finds that the financial risks to the utility associated with the consequences of a nuclear accident outweigh any financial gains that might be achieved by cutting corners on safety.

Although these arguments are superficially attractive, they are not supported by the facts. Unfortunately, financial considerations can and do lead to safety weaknesses in some instances. There have been instances, some recently, in which regulated utility licensees with operating power reactors have emphasized maximizing electricity generation over safety, have been unwilling to build a strong, technically capable nuclear plant operations organization, or have failed to move aggressively to satisfy new NRC safety requirements. In many instances, financial considerations appear to be a significant contributor to these utility decisions. Some of these safety weaknesses have been of continuing duration, and not all have been identified or corrected by our inspection and enforcement program. These examples would appear to indicate clearly that financial considerations can and do affect safety in some instances. Given this experience, I see no basis for the majority's conclusion that the NRC need not examine a utility's financial capability to operate the plant or consider financial qualification issues in our licensing proceedings. Nor does the Commission's reliance on 10 CFR 2.758 provide an effective means for identifying and correcting safety weaknesses caused by financial considerations. As it would apply here, 10 CFR 2.758 would require that a member of the public first identify the financial qualification issue, bring it to the Commission's attention and demonstrate that special circumstances exist in the case before *any* consideration of the issue will be permitted. This very restricted opportunity to raise the issue imposes a heavy burden on the party seeking to raise the issue, and the Commission's new rule, for all practical purposes, can be expected to eliminate virtually all consideration of financial qualification issues by the NRC staff and in operating license hearings. Finally, the majority argues that the elimination of the Commission's existing financial qualification reviews is justified on the ground that those reviews fail to consider how a utility actually spends the revenues provided by public utility commissions. However, if present financial qualification reviews are ineffective, that is an argument for restructuring, rather than eliminating, them.

Rather than seeking to eliminate virtually all consideration of financial qualification issues, the Commission should be restructuring its rules and regulatory programs to ensure that its financial qualification reviews identify any financial considerations that can affect the safety of plant operations. Such a restructured program could focus on five elements. The first element would be a required certification by the relevant public utility commission or commissions to the effect that revenues necessary to support the plant's prudent operation will be forthcoming. Such a certification would satisfy the purpose served by the Commission's previous financial qualification reviews. At the same time, unwillingness on the part of a utility commission to provide such a certification would indicate a potential financial qualification problem requiring further NRC review.

The second element would be to restore the opportunity for participants in NRC licensing proceedings to raise and litigate financial qualification issues, including questions regarding the utility's ability or unwillingness to apply the funds needed for safe plant operation, and questions involving regulatory or contractual commitments that could lead to unsafe operation. The third element would be to permit members of the public to raise financial qualification issues regarding operating plants and to have those issues considered pursuant to 10 CFR 2.206.

The fourth element would consist of an augmented NRC inspection program to consider the possible connection between financial considerations and identified plant safety weaknesses. The final element would consist of a required showing by the utility of how it intends to assure the availability of funds to pay the cost of plant decommissioning. This final element may best be considered as part of the Commission's decommissioning rule, but the Commission could commit to requiring such a showing now. It is worth noting that the majority was unwilling to indicate at this time a commitment to address the financial qualification issue for decommissioning in a subsequent decommissioning rule. Taken together, these elements or a restructured program would reflect the role and knowledge of the public utility commissions and would eliminate unnecessary duplication of effort. At the same time, this program would recognize the link between financial considerations and safety, and would provide for more effective consideration of financial qualification issues. Such an approach would demonstrate the Commission's desire to deal effectively with safety issues. Unfortunately, the Commission seems more inclined simply to avoid them.

Separate Statement of Chairman Palladino

Commissioner Asselstine's criticism of the Commission's approach is not justified by either the facts or the law in this rulemaking.

First, as the Court of Appeals observed in its decision remanding the Commission's March 1982 rule, even if the Atomic Energy Act of 1954 were interpreted as requiring financial qualification reviews, it would not preclude appropriate generalized criterie that would render some case-by-case evaluations unnecessary. *NECNP v. NRC*, Slip op. at 5 (February 7, 1984). The Commission rested its proposal of April 2, 1984 to eliminate financial qualifications reviews on the generic conclusion that the rate process assures for regulated electric utilities (or those utilities able to set their own rates) the funds needed for safe operation of a nuclear power facility. In the statement accompanying today's final rule, the Commission notes its belief that the rulemaking record supports this generic conclusion. It also notes that 10 CFR 2.758 provides an avenue for possible consideration of financial qualifications in a particular case where the generic conclusion appears not to apply. The Act does not require more.

Second, the Commission's financial qualification reviews have not, in the past, addressed questions about how a utility resolves conflicting financial priorities. The statement accompanying the final rule makes clear that the Commission relies on a number of regulatory means, including post-licensing inspection and enforcement, to protect against financial choices by a utility that are adverse to safe nuclear plant operation.

Third, I would point out that while the Commission requested comment on the question whether financial qualification reviews might be eliminated completely on the ground that no link has been shown between financial qualification reviews and assurance of safety, it did not base its proposed rule on that ground. The final rule's accompanying statement notes support for, but it does not seek to justify the final rule on, that ground. The accompanying statement also notes that, if a link can be identified in a particular case between financial qualification review and safe plant operation it could be addressed under 10 CFR 2.758.

Fourth, the matter of decommissioning costs is the subject of separate generic consideration within NRC. The fact that the Commission has chosen not to tie decommissioning costs to this financial qualifications rulemaking should not be interpreted as an indication that the Commission believes that decommissioning funding is unimportant to public health and safety. Rather, it recognizes that any action on decommissioning is more appropriate in the context of a separate generic rulemaking. See 47 F.R. 13750 (March 31, 1982).

Dated at Washington, DC this 6th day of September 1984.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,
Secretary of the Commission.

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49 FR 36631
Published 9/19/84

10 CFR Parts 2 and 50

Elimination of Review of Financial Qualifications of Electric Utilities in Operating License Review and Hearings for Nuclear Power Plants

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule: correction.

SUMMARY: This document corrects a final rule eliminating financial qualification review and findings for electric utilities that are applying for operating licenses for utilization facilities if the utility is a regulated public utility or is authorized to set its own rates. The final rule also restates a requirement for financial qualification review and findings for electric utilities that are applying for construction permits.

FOR FURTHER INFORMATION CONTACT: Carole F. Kagan, (202–634–1493).

SUPPLEMENTARY INFORMATION: In FR Doc. 84–24084 appearing on page 35747 in the issue of Wednesday, September 12, 1984, make the following correction:

The effective date should read October 12, 1984.

Approved: September 12, 1984.

John C. Hoyle,
Assistant Secretary.

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49 FR 38534
Published 10/1/84

10 CFR Parts 2 and 50

Elimination of Review of Financial Qualifications of Electric Utilities in Operating License Review and Hearings for Nuclear Power Plants

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule: correction.

SUMMARY: This document corrects a final rule eliminating financial qualification review and findings for electric utilities that are applying for operating licenses for utilization facilities if the utility is a regulated public utility or is authorized to set its own rates. The final rule also restates a requirement for financial qualification review and findings for electric utilities that are applying for construction permits.

FOR FURTHER INFORMATION CONTACT: Carole F. Kagan (202–634–1493).

SUPPLEMENTARY INFORMATION: In FR Doc. 84–24085 appearing on page 35747 in the issue of Wednesday, September 12, 1984, make the following correction:

Page 35751, first column, second complete paragraph, change the words "strong indications" to "some indication".

Approved: September 25, 1984.

John C. Hoyle,
Assistant Secretary.

➢ 50 FR 13006
Published 4/2/85
Effective 5/3/85

10 CFR Part 2

Exceptions to Notice and Comment Rulemaking Procedures

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The final rule amends the Commission's rules of practice by revising Commission rulemaking procedures contained in 10 CFR 2.804 and 2.805 to clarify the Commission's use of the exceptions to notice and comment rulemaking contained in section 4 of the Administrative Procedure Act, 5 U.S.C. 553(b). This clarification is necessary in light of the U.S. Court of Appeals for the District of Columbia decision in *Union of Concerned Scientists* v. *Nuclear Regulatory Commission*, 711 F. 2d 370 (D.C. Cir. 1983).

EFFECTIVE DATE: May 3, 1985.

FOR FURTHER INFORMATION CONTACT: Francis X. Cameron, Office of the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: 301–492–8689.

SUPPLEMENTARY INFORMATION:

I. Background

The U.S. Court of Appeals for the District of Columbia, in its decision in *Union of Concerned Scientists* v. *Nuclear Regulatory Commission*, 711 F. 2d 370 (D.C. Cir. 1983) ("*UCS* v. *NRC*"), vacated the Commission's rule of June 30, 1982, which amended operating licenses by removing the deadline for the environmental qualification of electric equipment (47 FR 28363, June 30, 1982). The D.C. Circuit held that by making the rule immediately effective instead of providing for notice and comment, the NRC had among other things, violated Commission regulations. This holding was based on language in 10 CFR 2.804 which the Court read, contrary to the Commission's interpretation, as a requirement for prior notice and opportunity for comment in all Commission rulemakings. The Court concluded that the NRC had divested itself of whatever discretion applicable statutes might allow for dispensing with notice and comment.

In response, the Commission issued a proposed rule to clarify its regulations so as to leave no doubt that the Commission does assert, to the extent allowable, its discretion under Section 4 of the Administrative Procedure Act (APA), 5 U.S.C. 553(b), to make exceptions to the general requirements for notice and opportunity for comment in informal rulemaking (49 FR 13043, April 2, 1984). In making this clarification, however, the Commission also noted that the D.C. Circuit in *UCS* v. *NRC* had called into question the extent to which the Commission can lawfully claim discretion to invoke the APA exceptions to notice and comment rulemaking. As an alternative reason for vacating the rule under review, the D.C. Circuit held that the notice and hearing requirements in Section 189a of the Atomic Energy Act of 1954, as amended, 42 U.S.C. 2239a, prevented the Commission from relying on the APA "good cause" exception in the June 30, 1982, rulemaking. In the Commission's view, however, the Court's explanation of this holding left unclear whether the Court saw Section 189a as a general bar to use of the APA "good cause" exception in any NRC rulemaking affecting the activities of licensees, or as a less sweeping restriction that would only apply to rulemakings which specifically amend reactor licenses. Consequently, the Commission moved the D.C. Circuit to vacate this part of its opinion. The Commission noted to the Court that the discussion of the relation between Section 189a and the APA "good cause" exception was unnecessary to the result of the case, raised issues which had not been briefed, was ambiguous in its scope, and could, if read broadly, interfere severely with the Commission's ability to act promptly in the interest of public health and safety. The Court then called for simultaneous briefing by the parties on the availability of the APA "good cause" exception in Commission rulemaking. The Commission filed a brief which maintained that Section 189a does not restrict use of the "good cause" exception. The Union of Concerned Scientists argued that there was a virtually total bar to use of the exception. After receiving this additional briefing, the Court on December 5, 1983 denied without opinion the Commission's motion to amend the decision, offering no further explanation or clarification of its holding, and ordered that its mandate should issue.

In the Supplementary Information to the proposed rule, the Commission noted its view that any reading of Section 189a which interferes with the Commission's ability to take immediate action affecting the activities of NRC licensees, whether by individual order or by rulemaking, when safety requires it, is contrary to the intent of Congress and is an erroneous interpretation of the Atomic Energy Act. A limitation on use of the APA "good cause" exception clearly has the potential for such interference and therefore should be interpreted narrowly.

Under these circumstances, it is reasonable to interpret the court's opinion no broader than the language and the context require. Accordingly, the Commission interprets the language in *UCS* v. *NRC* relevant to the availability of the "good cause" exception to apply only to the rulemaking under review in that case, *i.e.*, amendments of specific reactor licenses requiring prior notice by statute, while leaving unaffected the Commission's authority under the APA to make other kinds of rules effective without prior notice and comment when there is good cause. In response to the D.C. Circuit's opinion in *USC* v. *NRC*, the Commission proposed to include in 10 CFR 2.804 language providing that the APA exceptions to notice and comment rulemaking will apply only where notice and comment are not required by statute.

The proposed rule left intact for the most part the Commission's longstanding and consistent interpretation of its statutory authority and of rulemaking procedures contained in 10 CFR Part 2, Subpart H, that the Commission could avail itself of the exceptions to notice and comment rulemaking contained in the APA for—

- Interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice. 5 U.S.C. 553(b)(A); or
- When the agency for good cause finds that notice and comment are impracticable, unnecessary, or contrary to the public interest. 5 U.S.C. 553(b)(B).

To ensure that the regulation unambiguously reflected the Commission's intentions, the proposed rule amended 10 CFR 2.804 and 2.805 to provide explicitly for Commission discretion to invoke in appropriate situations the APA exceptions to notice and comment rulemaking cited above, as permitted by law. Under the proposed rule, notice and comment would not be mandatory in Commission rulemaking within the scope of section 553 of the U.S. Code, when they involve interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice, or where the Commission for good cause finds that notice and comment are impracticable, unnecessary or contrary to the public interest.

II. Comments

The Commission received five comments on the proposed rulemaking. Two of these were from the nuclear industry (Yankee Atomic Electric Company, Comment 2; Middle South Services, Comment 4), one from a private citizen (M.L. Lewis, Comment 1), one from a public interest group (Union of Concerned Scientists, Comment 5), and one from a Federal agency (Administrative Conference of the United States, Comment 3).

One of these commenters (M.L. Lewis) expressed the opinion that the proposed rule was an attempt to remove the public's right to comment on a rule before it becomes effective. The proposed rule simply incorporates into the Commission's regulations, the exceptions to notice and comment provided in the APA. These statutory exceptions, generally available to all agencies, are a congressional recognition that in some situations the normal public participation procedures should not be required in advance of taking the action. Public comment, however, will be sought post-promulgation pursuant to new Section 2.804(e) where it is necessary because of public interest in the rule. The Commission's normal practice, in keeping with Section 4 of the APA, is to provide for public participation in Commission rulemakings.

Another commenter, the Administrative Conference of the United States (ACUS), recommended that the final rule provide an opportunity for "post-promulgation" comment whenever the good cause exception of Section 4 of the APA was invoked because prior notice and comment was "impracticable" or "contrary to the public interest." However, such post-promulgation comment need not be provided when the good cause exception was invoked because prior notice and comment are "unnecessary." This corresponds to Administrative Conference Recommendation 83–2, 1 CFR 305, 83–2 (1984). Recommendation 83–2 stated that experience has confirmed the need for a "good cause" exception from the APA's notice and comment requirements. However, a post-promulgation comment opportunity "will give interested persons a chance to expose any errors or oversights that occurred in the formulation of the rule and to present policy arguments for changing the rule." *Id.* at 158. The post-promulgation comment opportunity should not extend to rules for which the agency determines public notice and comment to be "unnecessary" because such rules have been found by the courts to be minor or merely technical amendments in which the public has little interest.

The Commission agrees in principle with the recommendation of the ACUS. Accordingly, the final rule incorporates a new provision, 10 CFR 2.804(e), to provide for post-promulgation comment on rules when the "good cause" exception is invoked when prior notice and comment is "impracticable" or "contrary to the public interest." After receipt of comments, the Commission will publish a statement in the **Federal Register** which provides an evaluation of any significant issues raised by the public comments, as well as any revisions to the rule that have resulted from the staff evaluation of the public comments.

In addition, the ACUS recommended that the Commission should normally use notice and comment when adopting interpretative rules or general policy statements that are likely to have a substantial impact on the public, or at least to provide a post-promulgation comment opportunity if there has been no notice and comment prior to the adoption of such rules or statements. This corresponds to ACUS Recommendation 76–5, 1 CFR 305.76–5 (1984). The Commission normally provides for notice and opportunity for comment on policy statements and interpretative rules, and will continue to do so in the future. In order to retain the flexibility provided by the exception in Section 4 of the APA, the Commission has not adopted the ACUS recommendation completely. The Commission, in 10 CFR 2.804(e), provides for a post-promulgation comment opportunity for interpretative rules or general statements of policy issued without prior notice and comment, except when the Commission finds that post-promulgation comment would "serve no public interest or would be so burdensome as to outweigh any forseeable gain." This latter provision reflects ACUS Recommendation 76–5. *Id.*

A third commenter, the Union of Concerned Scientists (UCS), asserted that Section 189a of the Atomic Energy Act requires the Commission to provide notice and opportunity for comment with respect to *any* rulemaking proceeding dealing with the activities of licensees and consequently prohibits the Commission from restricting the limitation on the use of the APA exceptions to notice and comment rulemaking to rulemakings which amend reactor licenses. Section 189a(1) of the Atomic Energy Act provides, among other things, that:

> In any proceeding under this chapter, for the granting, suspending, revoking, or amending of any license or construction permit, or application to transfer control, *and in any proceeding for the issuance or modification of rules and regulations dealing with the activities of licensees*, and in any proceeding for the payment of compensation, an award or royalties under sections 2183, 2187, 2236(c) or 2238 of this title, *the Commission shall grant a hearing* upon the request of any person whose interest may be affected by the proceeding. (Emphasis added)

UCS argues that this provision constitutes a statutory bar to the use of the APA exceptions from notice and comment rulemaking. These exceptions are normally available, "except when notice or hearing is required by statute." 5 U.S.C. 553(b). According to the commenter, this proposition was affirmed in *UCS* v. *NRC* where the D.C. Circuit held that "[w]hether characterized as a license amendment or a rulemaking, the Commission's action runs afoul of the express terms of Section 189(a) which unequivocally requires notice and opportunity to comment for both types of proceedings." *Supra* at 380. Therefore, the commenter argues, the Commission cannot limit the decision in *UCS* v. *NRC* to the specific type of rule at issue in that case, i.e. rules which specifically amend reactor licenses. Furthermore, the commenter does not believe that the Commission needs the APA "good cause" exception to take immediate action when safety requires it: In support, the commenter cited the Commission's ability to issue an "immediately effective license amendment" when no significant hazards are involved or to issue an "immediately effective order."

In response, the Commission first reiterates its earlier statement that it is reasonable to give the Court's opinion in *UCS* v. *NRC* an interpretation no more restrictive than the language and context appear to require. As noted earlier, the Court's explanation of its holding left unclear whether the Court saw section 189a of the Atomic Energy Act as a general bar to the use of the APA "good cause" exception in any NRC rulemaking affecting the activities of licensee, or as a less sweeping restriction, which would only apply to rulemakings which specifically amend reactor licenses. The Commission would note that Section 181 of the Atomic Energy Act states that "[t]he provisions of the Administrative Procedure Act . . . shall apply to all agency action taken under this Act." 42 U.S.C. 2231. It is well-established that Commission rulemaking is governed by the APA requirements for informal rulemaking, set out in 5 U.S.C. 533, in which the exceptions to notice and comment appear.[1] Unless the APA exceptions are withdrawn by language elsewhere in the Atomic Energy Act, it should be presumed the Congress intended the exceptions to be available. The Commission does not believe that the language of Section 189a, or any other language in the Atomic Energy Act, compels a finding that Congress intended to deprive the Commission of the rulemaking flexibility permitted by the APA. Nothing in the language of Section 189a or the legislative history specifies that in rulemaking the Commission is to be limited by the constraints of the APA, but denied the opportunity to use the flexibility provided by the APA. The Commission's interpretation of the Atomic Energy Act as not prohibiting the promulgation of a rule without notice and opportunity to comment when APA "good cause" requirements have been met has been consistent and longstanding, and is reflected in Commission practice.[2]

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[1] *See*, e.g. *Vermont Yankee Nuclear Power Corp.* v. *NRDC*. 435 U.S. 519 (1978).

[2] For example, see the following instances where the Commission has invoked the APA exceptions to notice and comment rulemaking: Amendment to Definition of Production Facility, 26 FR 4989 (June 6, 1961); Siting of Reprocessing Plants and Related Waste Management Facilities, 36 FR 5411 (March 23, 1971); Prohibition of Site Preparation and Related Activities, 37 FR 5745 (March 21, 1972); Exemption for Facilities Processing Irradiated Materials Containing Limited Quantities of Special Nuclear Materials, 39 FR 4871 (February 8, 1974); Application of Certain Cost—Benefit Analysis Requirements of Appendix I to Certain Nuclear Power Plants, 40 FR 40816 (September 4, 1975); Codes and Standards for Nuclear Power Plants, 41 FR 23831 (June 14, 1976); Revocation of Certain Reporting Requirements, 43 FR 49175 (October 25, 1978); Amendment to Definition of Basic Components, 43 FR 48621 (October 10, 1978); Domestic Licensing Proceedings: Modified Adjudicatory Procedures, 44 FR 65050 (November 9,

The interpretation on which UCS insists cannot be reconciled with the Nuclear Regulatory Commission's clear responsibility to act swiftly to protect public health and safety when it perceives that a regulated activity presents an undue risk. Under the regulatory framework established by the Atomic Energy Act, the Commission's primary means of responding to hazards is by suspending, revoking, or amending licenses. The notice and hearing requirements for such actions are set out in Section 189a(1) of the Act in the same language that applies to rulemaking dealing with the activities of licensees. Accordingly, if Congress intended the language of Section 189a(1) to be read, as the commentor would read it, as an, absolute bar on the Commission's ability to promulgate regulations without delay even when there is good cause for doing so, the same bar apparently would apply to immediate action by the Commission to suspend or revoke licenses in circumstances where delay could have grave consequences. This cannot have been Congress' intention. Even the commentor recognizes that such a restriction would be fundamentally at odds with the Commission's responsibilities.[3] The Commission therefore rejects their interpretation of Section 189(a) as overriding the APA good cause exception and requiring prior notice and comment in all Commission licensing and rulemaking activities, regardless of circumstances.

The language the commenter cites from *UCS* v. *NRC that* "[w]hether characterized as a license amendment or a rulemaking, the Commission's action runs afoul of the express terms of section 189a which unequivocally requires notice and comment for both types of proceedings," *supra* at 380, must be read in the context of the Court's reference to Section 187 of the Atomic Energy Act, 42 U.S.C. 2237. Section 187 explicitly provides that "the terms and conditions of all licenses shall be subject to amendment, revision, or modification, . . . by reason of rules and regulations issued in accordance with the terms of this Act." As the Court noted:

> We express no opinion on the arguments of the parties on the question whether these amendments must be made by adjudication or whether they fall within that category of license amendments that may be made by rule under section 187 of the Atomic Energy Act, 42 U.S.C. § 2237 (1976). That is a matter for the NRC to determine in the first instance on remand. We merely hold here that notice and an opportunity to comment must be provided whatever administrative route is taken. Section 187 provides that "[t]he terms and conditions of all licenses shall be subject to amendment . . . by reason of rules and regulations *issued in accordance with the terms of this chapter* [sic]." 42 U.S.C. § 2237 (emphasis added). Since section 189(a) requires a hearing "in any proceeding for the issuance . . . of rules and regulations dealing with the activities of licensees," id. § 2239(a), a license amendment effected pursuant to section 187 but without notice and comment would not be "issued in accordance with the terms of this chapter." *Id.*

In order to comply with the Court's decision, 10 CFR 2.804 of the final rule provides for prior notice and comment whenever a rulemaking would specifically amend reactor licenses. However, as noted earlier, the Commission believes it is reasonable to give the Court's opinion an interpretation no more restrictive than the language and context requires.

Any reading of Section 189a, which interferes with the Commission's ability to take immediate action affecting the activities of NRC licensees, whether by order or by rulemaking, when safety requires it, is contrary to the intent of Congress. A limitation on use of APA "good cause" exception clearly has the potential to interfere with the Commissions safety responsibilities and therefore should be interpreted narrowly. The existence of the other mechanisms cited by the commenter that would enable the Commission to act quickly in the event of a safety emergency is not a sufficient rationale to deny the Commission the availability of all mechanisms provided by law, such as the use of the APA exceptions to notice and comment rulemaking.

On a separate matter, UCS also objected to a provision currently in 10 CFR 2.804 which allows the Commission to use means of providing notice of proposed rulemaking other than publication in the **Federal Register**. Section 2.804(a) provides that:

> when the Commission proposes to adopt, amend, or repeal a regulation it will cause to be published in the **Federal Register** a notice of proposed rulemaking unless all persons subject to the notice are named and either personally served or otherwise have actual notice in accordance with law.

According to the commenter, Section 189a of the Atomic Energy Act requires the Commission to provide a notice and comment hearing to any person whose interest may be affected by the proceeding. Because this could include all members of the public affected by the proceeding, the commenter argues that it is misleading to suggest that the Commission could avoid **Federal Register** publication by attempting personal service of all affected members of the public. In addition, the commenter asserts that the provision would be illegal if the Commission intends to implement the rule by giving notice only to the licensees governed by particular rules.

This provision is within the permissible scope of 5 U.S.C. 552(a), is not an issue that was addressed in *USC* v. *NRC*, and does not fall within the ambit of this rulemaking. Therefore, this provision is unaffected by this rulemaking and is retained as part of Commission regulations.

Another commenter, (Yankee Atomic) writing in support of the rule, stated that the notice and comment requirements of Section 4 of the Administrative Procedure Act must be followed whenever a Commission rulemaking ". . . changes existing rights and obligations . . ." for licensees. The basis for this statement, and the source of the quoted material, is the decision in *Lewis—Mota* v. *Secretary of Labor*, 469 F.2d 478, 482 (2d. Cir. 1972). In response, the Commission reiterates that any limitations on the use of the APA exceptions from notice and comment inferred from *UCS* v. *NRC* only apply to the kind of rulemaking under review in that case, i.e. rules that specifically amend reactor licenses. Under the final rule, the Commission can avail itself of the APA exemptions, if the requisite criteria are met, for any other rulemakings even if they do affect the "rights and obligation" of licensees. The case cited by the commenter, *Lewis-Mota* v. *Secretary of Labor*, focused on an application of the APA exception from notice and comment rulemaking for *interpretative* rules. The issue in the case was whether the particular rule

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1979); Packaging of Radioactive Materials for Transport and Transportation of Radioactive Materials Under Certain Conditions, 44 FR 63083 (November 2, 1979); Physical Protection of Irradiated Reactor Fuel in Transit, 44 FR 34466 (June 15, 1979); Emergency Planning and Preparedness for Production and Utilization Facilities, 46 FR 63031 (December 30, 1981); Commission Review Procedures for Power Reactor Construction Permits and Operating Licenses 47 FR 40535 (September 15, 1982); Filing of Copies of Changes to Emergency Plans and Procedures, 47 FR 57670 (December 29, 1982).

[3] The Union of Concerned Scientists states in its comments that the Commission retains authority to take immediate safety action, but apparently believes that language in Section 189a authorizing immediately effective license amendments that involve "no significant hazards consideration" gives the Commission its sole power to act immediately to protect safety. This language was not included in the 1954 statute and did not appear until the 1962 amendments. Thus, UCS's approach implies that prior to 1962 the Commission had no power at all to take immediate safety action affecting licensees and that after 1962, Congress allowed such action only through the device of amending licenses, even if a temporary license suspension would be more appropriate. This approach is contradictory to the emphasis on safety and flexibility apparent throughout the Act, its legislative history, and longstanding Commission practice prior to 1962. A more reasonable approach which the Commission adopts, is that Congress intended from the beginning that the APA exceptions for immediately effective action should be available to the Commission and were not to be overridden by Section 189.

was a "substantive" rule or an "interpretative" rule. The phrase cited by the commenter was made in the context of determining whether the rule was a "substantive" rule, i.e., whether it "changes existing rights and obligations." In applying the exemptions contained in Section 4 of the APA, the Commission will follow all applicable law, including judicial decisions, in determining whether a rule is an interpretative rule or a substantive rule as a part of its determination concerning what rulemaking procedures are applicable.

Finally, one commenter (Middle South Services), although supporting the rule, recommended that 10 CFR 2.805 be amended to ensure that public participation in Commission rulemaking is of a "timely" fashion. The Commission does not believe that it is necessary to amend Section 2.805 to include the word "timely." Each Commission rulemaking establishes appropriate requirements for timely participation.

III. Final Rule

Section 2.804(d). This section provides for Commission discretion to invoke, in appropriate situations, the APA exceptions to notice and comment rulemaking as permitted by law. Under the final rule, notice and comment would not be mandatory in Commission rulemaking within the scope of section 553 of the U.S. Code, when they involve interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice, or where the Commission for good cause finds that notice and comment are impracticable, unnecessary or contrary to the public interest. However, the use of such exceptions is not available when notice and comment are required by statute. The Commission interprets the *UCS* v. *NRC* case as establishing such a limitation on the use of the APA exceptions only for rules which specifically amend reactor licenses. The exceptions to notice and comment will be available for use, in appropriate situations for all other rules, including those that deal with the activities of licensees.

Section 2.804(e). This section provides for post-promulgation comment for all rules issued on the basis of the good cause exception when prior notice and comment was "impracticable" or "contrary to the public interest." Section 2.804(e) will also provide a post-promulgation comment opportunity for policy statements and interpretative rules that are issued without prior notice and comment. However, this opportunity for post-promulgation comment on interpretive rules and policy statement is not required if the Commission finds that such procedures would serve no public interest or would be so burdensome as to outweigh any forseeable gain.

Section 2.804(f). This section provides for a Commission evaluation of all significant issues raised by the comments received under the post-promulgation procedures of § 2.804(e).

Section 2.805(a). This section has been revised to reflect the revisions made to § 2.804.

Environmental Impact: Categorical Exclusion

The NRC has determined that this final rule is the type of action described in categorical exclusion 10 CFR 51.22(c)(1). Therefore neither an environmental impact statement nor an environmental assessment has been prepared for this final rule.

Paperwork Reduction Act Statement

This final rule contains no information collection requirements and therefore is not subject to the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this rule will not have a significant economic impact upon a substantial number of small entities. It merely clarifies and affirms existing Commission practice on utilizing the statutory exceptions to notice and comment rulemaking contained in Section 4 of the Administrative Procedure Act, 5 U.S.C. 553.

List of Subjects in 10 CFR Part 2

Administrative practice and procedure, Antitrust, Byproduct material, Classified information, Environmental protection, Nuclear materials, Nuclear power plants and reactors, Penalty, Sex discrimination, Source material, Special nuclear material, Waste treatment and disposal.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is adopting the following amendments to 10 CFR Part 2.

➢50 FR 18852
Published 5/3/85
Effective 10/12/84

10 CFR Parts 2 and 50

Elimination of Review of Financial Qualifications of Electric Utilities in Operating License Review and Hearings for Nuclear Power Plants; Correction

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule: Correction.

SUMMARY: This document corrects a final rule eliminating financial qualification review and findings for electric utilities that are applying for operating licenses for utilization facilities if the utility is a regulated public utility or is authorized to set its own rates. The final rule also reinstates a requirement for financial qualification review and findings for electric utilities which are applying for construction permits. This action is necessary in order to correct an inadvertent omission which could prevent the effectuation of one of the stated purposes of the rule: to reinstate a requirement for financial qualification review and findings for electric utility applicants for construction permits.

EFFECTIVE DATE: October 12, 1984.

FOR FURTHER INFORMATION CONTACT: Carole F. Kagan, Office of General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone: (202) 634-1493.

SUPPLEMENTARY INFORMATION: Accordingly, the following corrections are made in the document published on September 12, 1984 (49 FR 35747).

PART 2—[AMENDED]

1. On page 35752, § 2.104, (b)(1)(iii) is corrected to read as follows:

§ 2.104 Notice of hearing.

* * * * *

(b) * * *

(1) * * *

(iii) Whether the applicant is financially qualified to design and construct the proposed facility:

* * * * *

2. On page 35752, 10 CFR Part 2, Appendix A, VI.(c)(1)(iii) is corrected to read as follows:

* * * * *

VI. Posthearing Proceedings, Including the Initial Decision

* * * * *

(c) * * *

(1) * * *

(iii) Whether the applicant is financially qualified to design and construct the proposed facility;

* * * * *

PART 50—[AMENDED]

3. On page 35753, 10 CFR Part 50, Appendix C I.A.2. is corrected to read as follows:

* * * * *

I. * * *

A. * * *

2. *Source of construction funds.* The application should include a brief statement of the applicant's general financial plan for financing the cost of the facility, indentifying the source or sources upon which the applicant relies for the necessary construction funds, e.g., internal sources such as undistributed earnings and depreciation accruals, or external sources such as borrowings.

* * * * *

4. On page 35754, 10 CFR Part 50, Appendix C is corrected by adding items III. and IV. to read as follows:

III. Annual Financial Statement

Each holder of a construction permit for a production or utilization facility of a type described in § 50.21(b) or § 50.22, or a testing facility is required by § 50.71(b) to file its annual financial report with the Commission at the time of issuance thereof. This requirement does not apply to licensees or holders of construction permits for medical and research reactors.

IV. Additional Information

The Commission may, from time to time, request the applicant, whether an established organization or newly formed entity, to submit additional or more detailed information respecting its financial arrangements and status of funds if such information is deemed necessary to enable the Commission to determine an applicant's financial qualifications for the license.

5. On page 35754, 10 CFR Part 50, Appendix M 4.(b) is corrected to read as follows:

* * * * *

4. * * *

(b) The financial information submitted pursuant to § 50.33(f) and Appendix C shall be directed at a demonstration of the financial qualifications of the applicant for the manufacturing license to carry out the manufacturing activity for which the license is sought.

* * * * *

Dated at Washington, DC, this 29th day of April 1985.

For the Nuclear Regulatory Commission.

Martin G. Malsch,

Deputy General Counsel.

PART 4

NONDISCRIMINATION IN FEDERALLY ASSISTED COMMISSION PROGRAMS

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Appendix—A Federal Financial Assistance to Which This Part Applies

Authority: Sec. 161, Pub. L. 83–703, 68 Stat. 948, as amended (42 U.S.C. 2201); sec. 274, Pub. L. 86–373, 73 Stat. 688, as amended (42 U.S.C. 2021); sec. 207, Pub. L. 95–604, 92 Stat. 3033; sec. 201, Pub. L. 93–438, 88 Stat. 1242 (42 U.S.C. 5841); Subpart A also issued under secs. 602–605, Pub. L. 88–352, 78 Stat. 252, 253 (42 U.S.C. 2000d–1–2000d–4) and sec. 401, Pub. L. 93–438, 88 Stat. 1254 (42 U.S.C. 5891); Subpart B also issued under sec. 504, Pub. L. 93–112, 87 Stat. 394 (29 U.S.C. 794); sec. 111(a), Pub. L. 93–516, 88 Stat. 1619 (29 U.S.C. 706); sec. 119, Pub. L. 95–602, 92 Stat. 2982 (29 U.S.C. 794); and sec. 122, Pub. L. 95–602, 92 Stat. 2984 (29 U.S.C. 706(6)).

General Provisions

§ 4.1 Purpose and scope.

The regulations in this part implement: (a) The provisions of Title VI of the Civil Rights Act of 1964, Pub. L. 88–352, and Title IV of the Energy Reorganization Act of 1974, Pub. L. 93–438, which relate to nondiscrimination with respect to race, color, national origin or sex in any program or activity receiving Federal financial assistance from NRC; and (b) the provisions of section 504 of the Rehabilitation Act of 1973, as amended, Pub. L. 93–112, Pub. L. 95–602, which relates to nondiscrimination with respect to the handicapped in any program or activity receiving Federal financial assistance.

45 FR 14533

§ 4.1a Subparts.

Subpart A sets forth rules applicable to Title VI of the Civil Rights Act of 1964 and Title IV of the Energy Reorganization Act of 1974. (The Acts are collectively referred to in Subpart A as the "Act"). Subpart B sets forth rules applicable specifically to matters pertaining to section 504 of the Rehabilitation Act of 1973, as amended.

§ 4.2 Application of this part.

This part applies to any program for which Federal financial assistance is authorized under a law administered by NRC. The programs to which this part applies are listed in Appendix A of this part; Appendix A may be revised from time to time by notice published in the **Federal Register**. This part applies to money paid, property transferred, or other Federal assistance extended under any program or activity, by way of grant, loan, or contract by NRC, or an authorized contractor or subcontractor of NRC, the terms of which require compliance with this part. If any statutes implemented by this part are otherwise applicable, the failure to list a program in Appendix A does not mean the program is not covered by this part. This part does not apply to:

(a) Contracts of insurance or guaranty; or

(b) Procurement contracts; or

(c) Employment practices under any program or activity except as provided in § 4.13 and § 4.122.

45 FR 14533

§ 4.3 Definitions.

(a) "Applicant" means one who submits an application, request, or plan required to be approved by NRC, or by a primary recipient, as a condition to eligibility for Federal financial assistance; "application" means such an application, request, or plan.

(b) "Commission" means the Commission of five members or a quorum thereof sitting as a body; "NRC" means the Nuclear Regulatory Commission and its duly authorized representatives.

(c) "Facility" includes all or any portion of structures, equipment, or other real or personal property or interests therein, and the provisions of facilities includes the construction, expansion, renovation, remodeling, alteration or acquisition of facilities.

(d) "Federal financial assistance" includes: (1) Grants and loans of Federal funds, (2) the grant or donation of Federal property and interests in property, (3) the detail of Federal personnel or of other personnel at Federal expense, (4) the sale and lease of, and the permission to use (on other than a casual or transient basis), Federal property or any interest in such property without consideration or at a nominal consideration, or at a consideration which is reduced for the purpose of assisting the recipient, or in recognition of the public interest to be served by such sale or lease to the recipient, and (5) any Federal agreement, arrangement, or other contract which has as one of its purposes the provision of assistance.

29 FR 19277

(e) "Administrative Law Judge" means an individual appointed pursuant to section 11 of the Administrative Procedure Act to conduct proceedings subject to this part.

38 FR 2330

(f) "Primary recipient" means any recipient which is authorized or required to extend Federal financial assistance to another recipient for the purpose of carrying out a program.

(g) "Program" includes any program, project, or activity designated in Appendix A of this part for the provision of services, financial aid, or other benefits to individuals (including education or training) whether provided through employees of the recipient or provided by others through contracts or other arrangements with the recipient, and including work opportunities and cash or loan or other assistance to individuals, or for the provision of facilities for furnishing services, financial aid or other benefits to individuals. The services, financial aid, or other benefits provided under a program receiving Federal financial assistance shall be deemed to include any services, financial aid, or other benefits provided with the aid of Federal financial assistance or with the aid of any non-Federal funds, property, or other resources required to be extended or made available for the program to meet matching requirements or other conditions which must be met in order to receive the Federal financial assistance, and to include any services, financial aid, or other benefits provided in or through a facility provided with the aid of Federal financial assistance or such non-Federal resources.

(h) "Recipient" means any State, political subdivision of any State, or instrumentality of any State or political subdivision, any public or private agency, institution, or organization, or other entity, or any individual, in any State, to whom Federal financial assistance is extended, directly or through another recipient, for any program, including any successor, assignee, or transferee thereof, but such term does not include any ultimate beneficiary under any such program.

29 FR 19277

(i) "Responsible NRC official" means the Director of the Office of Equal Employment Opportunity or any other officer to whom the Executive Director for Operations has delegated the authority to act.

45 FR 14533

(j) "United States" means the States of the United States, the District of Columbia, Puerto Rico, the Virgin Islands, American Samoa, Guam, Wake Island, and the territories and possessions of the United States, and the term "State" means any one of the foregoing.

45 FR 18905

§ 4.4 Communications and reports.

Except where otherwise indicated, all communications and reports relating to this part shall be addressed to the United States Nuclear Regulatory Commission, Washington, D.C., 20555. Communications and reports may be delivered in person to the Commission's offices at 1717 H Street, NW., Washington, D.C., or its offices at 7920 Norfolk Avenue, Bethesda, Md.

40 FR 8774

§ 4.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). OMB has approved the information collection requirements contained in this part under control number 3150–0053.

(b) The approved information collection requirements contained in this part appear in §§ 4.32, 4.34, 4.125, 4.127, 4.231, and 4.232.

49 FR 19623

Subpart A—Regulations Implementing Title VI of the Civil Rights Act of 1964 and Title IV of the Energy Reorganization Act of 1974

45 FR 14533

DISCRIMINATION PROHIBITED

§ 4.11 General prohibition.

No person in the United States shall, on the ground of sex, race, color, or national origin, be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination under any program to which this subpart applies.

§ 4.12 Specific discriminatory actions prohibited.

(a) A recipient under any program to which this subpart applies may not, directly or through contractual or other arrangements, on the ground of sex, race, color, or national origin:

(1) Deny an individual any service, financial aid, or other benefit provided under the program;

(2) Provide any service, financial aid, or other benefit to an individual which is different, or is provided in a different manner, from that provided to others under the program;

(3) Subject an individual to segregation or separate treatment in any matter related to his receipt of any service, financial aid, or other benefit under the program;

29 FR 19277

(4) Restrict an individual in any way in the enjoyment of any advantage or privilege enjoyed by others receiving any service, financial aid, or other benefit under the program;

(5) Treat an individual differently from others in determining whether he satisfies any admission, enrollment, quota, eligibilty, membership or other requirement or condition which individuals must meet in order to be provided any service, financial aid, or other benefit provided under the program;

(6) Deny an individual an opportunity to participate in the program through the provision of services or otherwise or afford him an opportunity to do so which is different from that afforded others under the program (including the opportunity to participate in the program as an employee but only to the extent set forth in § 4.13).

(b) A recipient in determining the types of services, financial aid, or other benefits, or facilities which will be provided under any such program, or the class of individuals to whom, or the situations in which, such services, financial aid, other benefits, or facilities will be provided under any such program, or the class of individuals to be afforded an opportunity to participate in any such program, may not, directly or through contractual or other arrangements, utilize criteria or methods of administration which have the effect of subjecting individuals to discrimination because of their sex, race, color, or national origin, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program as respects individuals of a particular sex, race, color, or national origin.

29 FR 19277

(c) In determining the site or location of facilities, a recipient or applicant may not make selections with the purpose or effect of excluding individuals from, denying them the benefits of, or subjecting them to discrimination under any program to which this subpart applies, on the grounds of sex, race, color, or national origin; or with the purpose or effect of defeating or substantially impairing the accomplishment of the objectives of the Act or this subpart.

(d) As used in this section the services, financial aid, or other benefits provided under a program receiving Federal financial assistance shall be deemed to include any services, financial aid, or other benefit provided in or through a facility provided with the aid of Federal financial assistance.

(e) The enumeration of specific forms of prohibited discrimination in this section and § 4.13 does not limit the generality of the prohibition in § 4.11.

38 FR 17927

(f) This subpart does not prohibit the consideration of sex, race, color, or national origin if the purpose and effect are to remove or overcome the consequences of practices or impediments which have restricted the availability of, or participation in, the program or activity receiving Federal financial assistance, on the grounds of sex, race, color or national origin. Where previous discriminatory practice or usage tends, on the grounds of sex, race, color, or national origin, to exclude individuals from participation in, to deny them the benefits of, or to subject them to discrimination under any program or activity to which this subpart applies, the applicant or recipient has an obligation to take reasonable action to remove or overcome the consequences of the prior discriminatory practice or usage, and to accomplish the purposes of the Act.

§ 4.13 Employment practices.

(a) Where a primary objective of a program of Federal financial assistance to which this subpart applies is to provide employment, a recipient may not, directly or through contractual or other arrangements, subject an individual to discrimination on the ground of sex, race, color, or national origin in its employment practices under such program (including recruitment or recruitment advertising, employment, layoff or termination, upgrading, demotion, or transfer, rates of pay or other forms of compensation, and use of facilities), including programs where a primary objective of the Federal financial assistance is (1) to assist such individuals through employment to meet expenses incident to the commencement or continuation of their education or training, or (2) to provide work experience which contributes to the education or training of such individuals. (Examples of such programs are nuclear training equipment grants, grants and loans of materials for training, and fellowship programs.) The requirements applicable to construction employment under any such program shall be those specified in or pursuant to Part III of Executive Order 11246 or any Executive order which supersedes it.

(b) Where a primary objective of the Federal financial assistance is not to provide employment, but discrimination on the grounds of sex, race, color, or national origin in the employment practices of the recipient or other persons subject to this subpart tends, on the grounds of sex, race, color, or national origin, to exclude individuals from participation in, to deny them the benefits of, or to subject them to discrimination under any program to which this subpart applies, the provisions of paragraph (a) of this section shall apply to the employment practices of the recipient or other persons subject to this subpart to the extent necessary to assure equality of opportunity to, and nondiscriminatory treatment of, beneficiaries.

45 FR 14533

§ 4.14 Medical emergencies.

A recipient shall not be deemed to have failed to comply with § 4.11 if immediate provision of a service or other benefit to an individual is necessary to prevent his death or serious impairment of his health, and such service or other benefit cannot be provided except by or through a medical institution which refuses or fails to comply with § 4.11.

29 FR 19277

ASSURANCE REQUIRED

§ 4.21 General requirements.

(a) Every grant, loan or contract under a program to which this subpart applies, except a program to which § 4.22 applies, shall, as a condition to its approval by NRC, or by the appropriate NRC contractor or subcontractor, and the extension of any Federal financial assistance pursuant thereto, contain or be accompanied by an assurance that the program will be conducted in compliance with all requirements imposed by or pursuant to this subpart. In the case of a grant, loan, or contract involving Federal financial assistance to provide real property or structures thereon, the assurance shall obligate the recipient, or, in the case of a subsequent transfer, the transferee, for the period during which the real property or structures are used for a purpose for which the Federal financial assistance is extended, or for another purpose involving the provision of similar services or benefits. In the case of personal property the assurance shall obligate the recipient for the period during which he retains ownership or possession of the property. In all other cases the assurance shall obligate the recipient for the period during which Federal financial assistance is extended pursuant to the grant, loan or contract. The Commission will specify the form of the foregoing assurances for each program and the extent to which like assurances will be required of subgrantees, contractors and subcontractors, successors in interest, and other participants in the program. Any such assurance shall include provisions which give the United States a right to seek its judicial enforcement.

45 FR 14533

(b) In the case of real property, structures or improvements thereon, or interests therein, which was acquired with Federal financial assistance, or in the case where Federal financial assistance is provided in the form of a transfer of real property or interest therein from the Federal Government, the instrument effecting or recording the transfer shall contain a covenant running with the land assuring nondiscrimination for the period during which the real property is used for a purpose for which the Federal financial assistance is extended or for another purpose involving the provision of similar services or benefits. Where no transfer of property is involved, but property is improved with Federal financial assistance, the recipient shall agree to include such a covenant in any subsequent transfer of such property. Where the property is obtained from the Federal Government, such convenant may also include a condition coupled with a right to be reserved by the NRC to revert title to the property in the event of a breach of the covenant where, in the discretion of the NRC, such a condition and right of reverter is appropriate to the program and to the nature of the grant and the grantee. In such event if a transferee of real property proposes to mortgage or otherwise encumber the real property as security for financing construction of new, or improvement of existing, facilities on such property for the purposes for which the property was transferred, the NRC may agree, upon request of the transferee and if necessary to accomplish such financing, and upon such conditions as the NRC deems appropriate, to forbear the exercise of such right to revert title for so long as the lien of such mortgage or other encumbrance remains effective. 38 FR 17927

(c) Transfers of surplus property are subject to regulations issued by the Administrator of General Services (41 CFR 101-6.2). 29 FR 19277

§ 4.22 Continuing State programs.

Every application by a State or a State agency for continuing Federal financial assistance shall require the submission of and every grant, loan, or contract to or with a State or a State agency to carry out a program involving continuing Federal financial assistance to which this subpart applies, shall, as a condition to its approval and the extension of any Federal financial assistance pursuant to the grant, loan or contract, contain or be accompanied by, a statement that the program is (or, in the case of a new program, will be) conducted in compliance with all requirements imposed by or pursuant to this subpart, and shall provide or be accompanied by provisions for such methods of administration for the program as are found by the responsible NRC official to give reasonable assurance that the recipient and all other recipients of Federal financial assistance under such program will comply with all requirements imposed by or pursuant to this subpart. 45 FR 14533

§ 4.23 [Deleted 40 FR 8774.]

§ 4.24 Assurances from institutions.

(a) In the case of a grant, loan or contract involving Federal financial assistance to an institution of higher education, the assurance required by § 4.21 shall extend to admission practices and to all other practices relating to the treatment of students.

(b) The assurance required with respect to an institution of higher education, hospital, or any other institution, insofar as the assurance relates to the institution's practices with respect to admission or other treatment of individuals as students, patients, or clients of the institution or to the opportunity to participate in the provision of services or other benefits to such individuals, shall be applicable to the entire institution unless the institution establishes, to the satisfaction of the responsible NRC official, that the institution's practices in designated parts or programs of the institution will in no way affect its practices in the program of the institution for which Federal financial assistance is sought, of the beneficiaries of or participants in such program. If in any such case the assistance sought is for the construction of a facility or part of a facility, the assurance shall in any event extend to the entire facility and to facilities operated in connection therewith. 29 FR 19277

§ 4.25 [Deleted 40 FR 8774.]

COMPLIANCE INFORMATION

§ 4.31 Cooperation and assistance.

The responsible NRC official shall to the fullest extent practicable seek the cooperation of recipients in obtaining compliance with this subpart and shall provide assistance and guidance to recipients to help them comply voluntarily with this subpart. 45 FR 14533

§ 4.32 Compliance reports.

Each recipient shall keep such records and submit to the responsible NRC official timely, complete and accurate compliance reports at such times, and in such form and containing such information, as the responsible NRC official may determine to be necessary to enable him to ascertain whether the recipient has complied or is complying with this subpart. In the case of any program under which a primary recipient extends Federal financial assistance to any other recipient, such other recipient shall also submit such compliance reports to the primary recipient as may be necessary to enable the primary recipient to carry out its obligations under this subpart.

§ 4.33 Access to sources of information.

Each recipient shall permit access by the responsible NRC official during normal business hours to such of its books, records, accounts, and other sources of information, and its facilities as may be pertinent to ascertain compliance with this subpart. Where any information required of a recipient is in the exclusive possession of any other agency, institution or person and that agency, institution or person shall fail or refuse to furnish this information, the recipient shall so certify in its report and shall set forth what efforts it has made to obtain the information. 45 FR 14533

§ 4.34 Information to beneficiaries and participants.

Each recipient shall make available to participants, beneficiaries, and other interested persons such information regarding the provisions of this subpart and its applicability to the program under which the recipient receives Federal financial assistance, and make such information available to them in such manner, as the responsible NRC official finds necessary to apprise such persons of the protections against discrimination assured them by the Act and this subpart.

CONDUCT OF INVESTIGATIONS

§ 4.41 Periodic compliance reviews.

The responsible NRC official shall from time to time review the practices of recipients to determine whether they are complying with this subpart.

§ 4.42 Complaints.

Any person who believes himself or any specific class of individuals to be subjected to discrimination prohibited by this subpart may by himself or by a representative file with the responsible NRC official a written complaint.

A complaint must be filed not later than ninety (90) days from the date of the alleged discrimination, unless the time for filing is extended by the responsible NRC official. A complaint shall be signed by the complainant or his representative.

§ 4.43 Investigations.

The responsible NRC official will make a prompt investigation whenever a compliance review, report, complaint, or any other information indicates a possible failure to comply with this subpart. The investigation should include, where appropriate, a review of the pertinent practices and policies of the recipient, the circumstances under which the possible noncompliance with this subpart occurred, and other factors relevant to a determination as to whether the recipient has failed to comply with this subpart.

§ 4.44 Resolution of matters.

(a) If an investigation pursuant to § 4.43 indicates a failure to comply with this subpart, the responsible NRC official will so inform the recipient and the matter will be resolved by voluntary means whenever possible. If it has been determined that the matter cannot be resolved by voluntary means, action will be taken as provided for in §§ 4.46-4.49.

(b) If an investigation does not warrant action pursuant to paragraph (a) of this section, the responsible NRC official will so inform the recipient and the complainant, if any, in writing.

45 FR 14533

§ 4.45 Intimidatory or retaliatory acts prohibited.

No recipient or other person shall intimidate, threaten, coerce, or discriminate against any individual for the purpose of interfering with any right or privilege secured by the Act or this subpart, or because he has made a complaint, testified, assisted, or participated in any manner in an investigation, proceeding, or hearing under this subpart. The identity of complainants shall be kept confidential, except to the extent necessary to carry out the purposes of this subpart including the conduct of any investigation, hearing, or judicial proceeding arising thereunder.

MEANS OF EFFECTING COMPLIANCE

§ 4.46 Means available.

If there appears to be a failure or threatened failure to comply with any of the provisions of this subpart, and if the noncompliance or threatened concompliance cannot be corrected by informal means, compliance with this subpart may be effected by the suspension or termination of or refusal to grant or to continue Federal financial assistance or by any other means authorized by law. Such other means may include, but are not limited to: (a) A reference to the Department of Justice with a recommendation that appropriate proceedings be brought to enforce any rights of the United States under any law of the United States (including other titles of the Act), or any assurance or other contractual undertaking, and (b) any applicable proceeding under State or local law.

§ 4.47 Noncompliance with § 4.21.

If an applicant fails or refuses to furnish an assurance required under § 4.21 or otherwise fails or refuses to comply with a requirement imposed by or pursuant to that section, Federal financial assistance may be refused in accordance with the procedures of § 4.48.

45 FR 14533

§ 4.48 Termination of or refusal to grant or to continue Federal financial assistance.

No order suspending, terminating, or refusing to grant or continue Federal financial assistance shall become effective until: (a) The responsible NRC official has advised the applicant or recipient of his failure to comply and has determined that compliance cannot be secured by voluntary means, (b) there has been an express finding on the record, after opportunity for hearing, of a failure by the applicant or recipient to comply with the requirement imposed by or pursuant to this subpart, (c) the action has been approved by the Commission pursuant to § 4.72, and (d) the expiration of thirty (30) days after the Commission has filed with the committee of the House and the committee of the Senate having legislative jurisdiction over the program involved, a full written report of the circumstances and the grounds for such action. Any action to suspend or terminate or to refuse to grant or to continue Federal financial assistance shall be limited to the particular political entity, or part thereof, or other applicant or recipient as to whom such finding has been made and shall be limited in its effect to the particular program, or part thereof, in which such noncompliance has been so found.

§ 4.49 Other means authorized by law.

No action to effect compliance by any other means authorized by law shall be taken until: (a) The responsible NRC official has determined that compliance cannot be secured by voluntary means, (b) the recipient or other person has been notified of its failure to comply and of the action to be taken to effect compliance, and (c) the expiration of at least ten (10) days from the mailing of such notice to the recipient or other person. During this period of at least ten (10) days, additional efforts shall be made to persuade the recipient or other person to comply with this subpart and to take such corrective action as may be appropriate.

45 FR 14533

OPPORTUNITY FOR HEARING

§ 4.51 Notice of opportunity for hearing.

(a) Whenever an opportunity for hearing is required by § 4.48, the responsible NRC official shall serve on the applicant or recipient, by registered or certified mail, return receipt requested, a notice of opportunity for hearing which will:

29 FR 19277

(1) Inform the applicant or recipient of his right within twenty (20) days of the date of the notice of opportunity for hearing, or such other period as may be specified in the notice, to request a hearing;

(2) Set forth the alleged item or items of noncompliance with this subpart;

(3) Specify the issues;

(4) State that compliance with this subpart may be effected by an order providing for the termination of or refusal to grant or to continue assistance, as appropriate, under the program involved; and

45 FR 14533

(5) Provide that the applicant or recipient may file a written answer to the notice of opportunity for hearing under oath or affirmation within twenty (20) days of its date, or such other period as may be specified in the notice.

(b) The applicant or recipient may respond to a notice of opportunity for hearing by filing a written answer under oath or affirmation. The answer shall specifically admit or deny each allegation, or, where the applicant or recipient does not have knowledge or information sufficient to form a belief, the answer may so state and the statements shall have the effect of a denial. Allegations of fact not denied shall be deemed to be admitted. The answer shall separately state and identify matters alleged as affirmative defenses and may also set forth the matters of fact and law on which the applicant or recipient relies. The answer may request a hearing.

29 FR 19277

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(c) If the answer requests a hearing, the Commission will issue a notice of hearing specifying:

(1) The time, place, and nature thereof;

(2) The legal authority and jurisdiction under which the hearing is to be held; and

(3) The matters of fact and law asserted or to be considered. The time and place of hearing will be fixed with due regard for the convenience and necessity of the parties or their representatives and for the public interest. An answer to a notice of hearing is not required.

38 FR 17927

(d) An applicant or recipient may file an answer, and waive or fail to request a hearing, without waiving the requirement for findings of fact and conclusions of law or the right to seek Commission review in accordance with the provisions of §§ 4.71-4.74. At the time an answer is filed the applicant or recipient may also submit written information or argument for the record if he does not request a hearing.

29 FR 19277

(e) An answer or stipulation may consent to the entry of an order in substantially the form set forth in the notice of opportunity for hearing; such order may be entered by the responsible Commission official. The consent of the applicant or recipient to the entry of an order shall constitute a waiver by him of a right to: (1) A hearing under the Act and § 4.48, (2) findings of fact and conclusions of law, and (3) seek Commission review.

38 FR 17927

(f) The failure of an applicant or recipient to file an answer within the period prescribed, or, if he requests a hearing, his failure to appear therefor, shall constitute a waiver by him of a right to: (1) A hearing under the Act and § 4.48, (2) conclusions of law, and (3) seek Commission review. In the event of such waiver, the responsible NRC official may find the facts on the basis of the record available and enter an order in substantially the form set forth in the notice of opportunity for hearing.

29 FR 19277

(g) An order entered in accordance with paragraph (e) or (f) of this section shall constitute the final decision of the Commission, unless the Commission, on its own motion, within forty-five (45) days after entry of the order, issues its own decision, which shall then constitute the final decision of the Commission.

(h) A copy of an order entered by the responsible NRC official shall be mailed to the applicant or recipient and to the complainant, if any.

(i) Nothing in this section shall be deemed to place the burden of proof on the applicant or recipient.

HEARINGS AND FINDINGS

38 FR 2330

§ 4.61 Presiding officer.

One or more members of the Commission or one or more administrative law judges appointed pursuant to section 3105 of title 5 of the United States Code shall: (a) Preside at a hearing and (b) make findings of fact and conclusions of law if an applicant or recipient waives a hearing and submits written information or argument for the record in accordance with § 4.51(d).

29 FR 19277

§ 4.62 Right to counsel.

In all proceedings under §§ 4.51-4.81, the applicant or recipient and the responsible NRC official shall have the right to be represented by counsel. A notice of appearance shall be filed by counsel prior to participation in any such proceedings.

38 FR 17927

§ 4.63 Procedures, evidence, and record.

(a) The hearing, decision, and any administrative review thereof shall be conducted in conformity with 5 U.S.C. 554-557 (sections 5-8 of the Administrative Procedure Act), and in accordance with such procedures as are proper (and not inconsistent with §§ 4.61-4.64) relating to the conduct of the hearing, giving of notices subsequent to those provided for in § 4.51, taking of testimony, exhibits, arguments and briefs, requests for finding, and other related matters.

29 FR 19277

Both the responsible NRC official and the applicant or recipient shall be entitled to introduce all relevant evidence on the issues as stated in the notice of hearing or as determined by the presiding officer at the outset of or during the hearing.

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(b) Technical rules of evidence shall not apply to hearings conducted pursuant to this subpart, but rules or principles designed to assure production of the most credible evidence available and to subject testimony to test by cross-examination shall be applied where reasonably necessary by the presiding officer. The presiding officer may exclude irrelevant, immaterial, or unduly repetitious evidence. All documents and other evidence offered or taken for the record shall be open to examination by the parties and opportunity shall be given to refute facts and arguments advanced on either side of the issues. A transcript shall be made of the oral evidence except to the extent the substance thereof is stipulated for the record.

29 FR 19277

(c) Each decision made after a hearing has been held shall be based on the hearing record, and written findings of fact and conclusions of law shall be made.

(d) If an applicant or recipient waives a hearing and submits written information or argument for the record in accordance with § 4.51(d), written findings of fact and conclusions of law shall be made.

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§ 4.64 Consolidated or joint hearings.

In cases in which the same or related facts are asserted to constitute noncompliance with this subpart with respect to two or more programs to which this subpart applies or noncompliance with this subpart and the regulations of one or more other Federal departments or agencies issued under Title VI of the Civil Rights Act of 1964, the Commission may, by agreement with such other departments or agencies, where applicable, provide for the conduct of consolidated or joint hearings, and for the application to such hearings of rules of procedure not inconsistent with this subpart. Final decisions in such cases, insofar as programs subject to this subpart are concerned shall be made in accordance with § 4.72.

29 FR 19277

DECISION AND NOTICE

§ 4.71 Initial decision or certification.

The officer designated:

(a) To preside at a hearing, or,

(b) To make findings of fact and conclusions of law if an applicant or recipient waives a hearing and submits written information or argument for the record in accordance with § 4.51(d), shall render an initial decision on the record, or, if the Commission so directs, shall certify the entire record to the Commission for decision, together with a recommended decision on the record. A copy of such initial decision, or of such certification and recommended decision, shall be mailed to the applicant or recipient.

§ 4.72 Exceptions and final decision.

(a) The applicant or recipient, within thirty (30) days of the mailing of an initial decision or a recommended decision, may file with the Commission his exceptions to such decision, with his reasons therefor.

(b) In the absence of exceptions to an initial decision, the Commission may, on its own motion within forty five (45) days after the mailing of such initial decision, serve on the applicant or recipient a notice that the Commission will review the decision.

(c) Upon the filing of exceptions to an initial decision or of a notice of review, the Commission shall review such initial decision and issue its own decision on the record with its reasons therefor.

(d) In the absence of either exceptions to an initial decision or of a notice of review, such initial decision shall constitute the final decision of the Commission.

(e) Upon the filing of exceptions to a recommended decision, the Commission shall review such recommended decision and issue its own decision on the record with its reasons therefor.

(f) In the absence of exceptions to a recommended decision, the Commission shall review such recommended decision and issue its own decision on the record with its reasons therefor.

29 FR 19277

§ 4.73 Rulings required.

Each decision of a presiding officer or the Commission shall set forth the rulings on each finding, conclusion, or exception presented, and shall identify the requirement or requirements imposed by or pursuant to this subpart with which it is found that the applicant or recipient has failed to comply.

§ 4.74 Content of orders.

The final decision may provide for suspension or termination of, or refusal to grant or continue Federal financial assistance, in whole or in part, under the program involved, and may contain such terms, conditions, and other provisions as are consistent with and will effectuate the purposes of the Act and this subpart, including provisions designed to assure that no Federal financial assistance will thereafter be extended under such program to the applicant or recipient determined by such decision to be in default in its performance of an assurance given by it pursuant to this subpart, or to have otherwise failed to comply with this subpart, unless and until it corrects its noncompliance and satisfies the NRC that it will fully comply with this subpart. A copy of the final decision shall be mailed to the applicant or recipient and the complainant, if any.

§ 4.75 Post termination proceedings.

(a) An applicant or recipient adversely affected by an order issued under § 4.74 shall be restored to full eligibility to receive Federal financial assistance if it satisfies the terms and conditions of that order for such eligibility or if it brings itself into compliance with this subpart and provides reasonable assurance that it will fully comply with this subpart.

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(b) Any applicant or recipient adversely affected by an order entered pursuant to § 4.74 may at any time request the responsible NRC official to restore fully its eligibility to receive Federal financial assistance. Any such request shall be supported by information showing that the applicant or recipient has met the requirements of paragraph (a) of this section. If the responsible NRC official determines that those requirements have been satisfied, he shall restore such eligibility.

(c) If the responsible NRC official denies any such request, the applicant or recipient may submit a request for a hearing in writing, specifying why it believes such official to have been in error. It shall thereupon be given an expeditious hearing, with the decision on the record, in accordance with rules of procedure issued by the responsible NRC official. The applicant or recipient will be restored to such eligibility if it proves at such a hearing that it satisfied the requirements of paragraph (a) of this section. While proceedings under this section are pending, the sanctions imposed by the order issued under § 4.74 shall remain in effect.

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JUDICIAL REVIEW

29 FR 19277

§ 4.81 Judicial review.

Action taken pursuant to section 602 of the Civil Rights Act of 1964 is subject to judicial review as provided in section 603 of that Act.

40 FR 8774

EFFECT ON OTHER REGULATIONS; FORMS AND INSTRUCTIONS

§ 4.91 Effect on other regulations.

All regulations, orders, or like directions heretofore issued by any officer of the NRC which impose requirements designed to prohibit any discrimination against individuals on the ground of sex, race, color, or national origin under any program to which this subpart applies, and which authorize the suspension or termination of or refusal to grant or to continue Federal financial assistance to any applicant for or recipient of such assistance under such program for failure to comply with such requirements, are hereby superseded to the extent that such discrimination is prohibited by this subpart, except that nothing in this subpart shall be deemed to relieve any person of any obligation assumed or imposed under any such superseded regulation, order, instruction, or like direction prior to the effective date of this subpart. Nothing in this subpart, however, shall be deemed to supersede any of the following (including future amendments thereof): (a) Executive Orders 10925, 11114, and 11246 and regulations issued thereunder, or (b) Executive Order 11063 and regulations issued thereunder and any other regulations or instructions insofar as such order, regulations or instructions prohibit discrimination on the ground of sex, race, color, or national origin in any program or situation to which this subpart is inapplicable, or prohibit discrimination on any other ground.

§ 4.92 Forms and instructions.

The responsible NRC official shall issue and promptly make available to interested persons forms and detailed instructions and procedures for effectuating this subpart as applied to programs to which this subpart applies and for which he is responsible.

§ 4.93 Supervision and coordination.

The Commission may from time to time assign to officials of other departments or agencies of the Government, with the consent of the department or agency involved, responsibilities in connection with the effectuation of the purposes of Title VI of the Civil Rights Act of 1964 and this subpart, other than responsibility for final decision as provided in § 4.72, including the achievement of effective coordination and maximum uniformity within the NRC and within the Executive Branch of the Government in the application of Title VI of the Civil Rights Act and this subpart to similar programs and in similar situations. Any action taken, determination made, or requirement imposed by an official of another department or agency acting pursuant to an assignment of responsibility under this section shall have the same effect as though such action had been taken by the responsible NRC official.

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Subpart B—Regulations Implementing Section 504 of the Rehabilitation Act of 1973, as amended

§ 4.101 Definitions.

As used in this subpart:

(a) "Handicapped person" means any person who has a physical or mental impairment that substantially limits one or more major life activities, has a record of such an impairment, or is regarded as having such an impairment. Such term does not include any individual who is an alcoholic or drug abuser whose current use of alcohol or drugs prevents such individual from performing the duties of the job in question or whose employment, by reason of such current alcohol or drug abuse, would constitute a direct threat to property or the safety of others.

(b) As used in paragraph (a) of this section, the phrase:

(1) "Physical or mental impairment" means (i) any physiological disorder or condition, cosmetic disfigurement, or anatomical loss affecting one or more of the following body systems: Neurological; musculoskeletal; special sense organs; respiratory, including speech organs; cardiovascular; reproductive; digestive, genitourinary; hemic and lymphatic; skin; and endocrine; or (ii) any mental or psychological disorder, such as mental retardation, organic brain syndrome, emotional or mental illness, and specific learning disabilities. The term "physical or mental impairment" includes, but is not limited to, such diseases and conditions as orthopedic, visual, speech, and hearing impairments, cerebral palsy, epilepsy, muscular dystrophy, multiple sclerosis, cancer, heart disease, diabetes, mental retardation, and emotional illness.

(2) "Major life activities" means functions such as caring for one's self, performing manual tasks, walking, seeing, hearing, speaking, breathing, learning, and working.

(3) "Has a record of such an impairment" means has a history of, or has been misclassified as having, a mental or physical impairment that substantially limits one or more major life activities. 45 FR 14533

(4) "Is regarded as having an impairment" means (i) has a physical or mental impairment that does not substantially limit major life activities but is treated by a recipient as constituting such a limitation; (ii) has a physical or mental impairment that substantially limits major life activities only as a result of the attitudes of others toward such impairment; or (iii) does not have a physical or mental impairment but is treated by a recipient as having such an impairment.

(c) "Qualified handicapped person" means (1) with respect to employment, a handicapped person who, with reasonable accommodation, can perform essential functions of the job in question and (2) with respect to services, a handicapped person who meets the essential eligibility requirements for the receipt of such services.

(d) "Section 504" means section 504 of the Rehabilitation Act of 1973, Pub. L. 93–112, as amended by the Rehabilitation, Comprehensive Services, and Developmental Disabilities Amendments of 1978, Pub. L. 95–602 (29 U.S.C. 794).

Discriminatory Practices

§ 4.121 General prohibitions against discrimination.

(a) No qualified handicapped person, shall, on the basis of handicap, be excluded from participation in, be denied the benefits of, or otherwise be subject to discrimination under any program or activity that receives or benefits from Federal financial assistance.

(b)(1) A recipient, in providing any aid, benefit, or service, may not, directly or through contractual, licensing, or other arrangements, on the basis of handicap:

(i) Deny a qualified handicapped person the opportunity to participate in or benefit from the aid, benefit, or service;

(ii) Afford a qualified handicapped person an opportunity to participate in or benefit from the aid, benefit, or service that is not equal to that afforded others;

(iii) Provide a qualified handicapped person with an aid, benefit, or service that is not as effective in affording equal opportunity to obtain the same result, to gain the same benefit, or to reach the same level of achievement as that provided to others; 45 FR 14533

(iv) Provide different or separate aid, benefits, or services to handicapped persons or to any class of handicapped persons than is provided to others unless such action is necessary to provide qualified handicapped persons with aid, benefits, or services that are as effective as those provided to others;

(v) Aid or perpetuate discrimination against a qualified handicapped person by providing significant assistance to any agency, organization, or person that discriminates on the basis of handicap in providing any aid, benefit, or service to beneficiaries of the recipient's program;

(vi) Deny a qualified handicapped person the opportunity to participate as a member of planning or advisory boards; or

(vii) Otherwise limit a qualified handicapped person in the enjoyment of any right, privilege, advantage, or opportunity enjoyed by others receiving the aid, benefit, or service.

(2) A recipient may not deny a qualified handicapped person the opportunity to participate in programs or activities that are not separate or different, despite the existence of permissibly separate or different programs or activities.

(3) A recipient may not directly or through contractual or other arrangements, utilize criteria or methods of administration (i) that have the effect of subjecting qualified handicapped persons to discrimination on the basis of handicap, (ii) that have the purpose or effect of defeating or substantially impairing accomplishment of the objectives of the recipient's program with respect to handicapped persons, or (iii) that perpetuate the discrimination of another recipient if both recipients are subject to common administrative control or are agencies of the same state.

(4) A recipient may not, in determining the site or location of a facility, make selections (i) that have the effect of excluding handicapped persons from, denying them the benefits of, or otherwise subjecting them to discrimination under any program or activity that receives or benefits from Federal financial assistance or (ii) that have the purpose or effect of defeating or substantially impairing the accomplishment of the objectives of the program or activity with respect to handicapped persons.

(c) The exclusion of nonhandicapped persons from the benefits of a program limited by Federal statute or Executive order to handicapped persons or the exclusion of a specific class of handicapped persons from a program limited by Federal statute or Executive order to a different class of handicapped persons is not prohibited by this subpart. 45 FR 14533

(d) Recipients shall administer programs and activities in the most integrated setting appropriate to the needs of qualified handicapped persons.

(e) Recipients shall take appropriate steps to ensure that communications with their applicants, employees, and beneficiaries are available to persons with impaired vision and hearing.

§ 4.122 General prohibitions against employment discrimination.

(a) No qualified handicapped person shall, on the basis of handicap, be subjected to discrimination in employment under any program or activity that receives or benefits from Federal financial assistance.

(b) A recipient shall make all decisions concerning employment under any program or activity to which this subpart applies in a manner which ensures that discrimination on the basis of handicap does not occur and may not limit, segregate, or classify applicants or employees in any way that adversely affects their opportunities or status because of handicap.

(c) The prohibition against discrimination in employment applies to the following activities:

(1) Recruitment, advertising, and the processing of applications for employment;

(2) Hiring, upgrading, promotion, award of tenure, demotion, transfer, layoff, termination, right of return from layoff, and rehiring;

(3) Rates of pay or any other form of compensation and changes in compensation;

(4) Job assignments, job classifications, organizational structures, position descriptions, lines of progression, and seniority lists;

(5) Leaves of absence, sick leave, or any other leave;

(6) Fringe benefits available by virtue of employment, whether or not administered by the recipient;

(7) Selection and financial support for training, including apprenticeship, professional meetings, conferences, and other related activities and selection for leaves of absence to pursue training;

(8) Employer sponsored activities, including social or recreational programs; and

(9) Any other term, condition, or privilege of employment.

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(d) A recipient may not participate in a contractual or other relationship that has the effect of subjecting qualified handicapped applicants or employees to discrimination prohibited by this subpart. The relationships referred to in this paragraph include relationships with employment and referral agencies, with labor unions, with organizations providing or administering fringe benefits to employees of the recipient, and with organizations providing training and apprenticeship programs.

§ 4.123 Reasonable accommodation.

(a) A recipient shall make reasonable accommodation to the known physical or mental limitations of an otherwise qualified handicapped applicant or employee unless the recipient can demonstrate that the accommodation would impose an undue hardship on the operation of its program.

(b) Reasonable accommodation may include: (1) Making facilities used by employees readily accessible to and usable by handicapped persons, and (2) job restructuring, part-time or modified work schedules, acquisition or modification of equipment or devices, the provision of readers or interpreters, and other similar actions. This list is neither all-inclusive nor meant to suggest that an employer must follow all the actions listed.

(c) In determining pursuant to paragraph (a) of this section whether an accommodation would impose an undue hardship on the operation of a recipient's program, factors to be considered include:

(1) The overall size of the recipient's program with respect to number of employees, number and type of facilities, and size of budget;

(2) The type of the recipient's operations, including the composition and structure of the recipient's workforce; and

(3) The nature and cost of the accommodation needed.

(d) A recipient may not deny any employment opportunity to a qualified handicapped employee or applicant if the basis for denial is the need to make reasonable accommodation to the physical or mental limitations of the employee or applicant.

§ 4.124 Employment criteria.

(a) A recipient may not make use of any employment test or other selection criterion that screens out or tends to screen out handicapped persons or any class of handicapped persons unless:

(1) The test score or other selection criterion as used by the recipient is shown to be job-related for the position in question, and

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(2) Alternative job-related tests or criteria that do not screen out or tend to screen out as many handicapped persons are not available.

(b) A recipient shall select and administer tests concerning employment so as best to ensure that, when administered to an applicant or employee who has a handicap that impairs sensory, manual, or speaking skills, the test results accurately reflect the applicant's or employee's job skills, aptitude, or whatever other factor the test purports to measure, rather than reflecting the applicant's or employee's impaired sensory, manual, or speaking skills (except where those skills are the factors that the test purports to measure).

§ 4.125 Preemployment inquiries.

(a) Except as provided in paragraphs (b) and (c) of this section, a recipient may not conduct a preemployment medical examination or may not make preemployment inquiry of an applicant as to whether the applicant is a handicapped person or as to the nature of severity of a handicap. A recipient may, however, make preemployment inquiry into an applicant's ability to perform job-related functions.

(b) When a recipient is taking remedial action to correct the effects of past discrimination, or when a recipient is taking voluntary action to overcome the effects of conditions that resulted in limited participation in its federally assisted program or activity, or when a recipient is taking affirmative action pursuant to section 503 of the Rehabilitation Act of 1973, the recipient may invite applicants for employment to indicate whether and to what extent they are handicapped: *Provided*, That:

(1) The recipient makes clear to the applicant that the information requested is intended for use solely in connection with its remedial action obligations or its voluntary or affirmative action efforts; and

(2) The recipient makes clear to the applicant that the information is being requested on a voluntary basis, that it will be kept confidential as provided in paragraph (d) of this section, that refusal to provide it will not subject the applicant to any adverse treatment, and that it will be used only in accordance with this subpart.

(c) Nothing in this section shall prohibit a recipient from conditioning an offer of employment on the results of a medical examination conducted prior to the employee's entrance on duty: *Provided*, That:

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(1) All entering employees are subjected to such an examination regardless of handicap, and

(2) The results of such an examination are used only in accordance with the requirements of this subpart.

(d) Information obtained in accordance with this section as to the medical condition or history of the applicant shall be collected and maintained on separate forms that shall be accorded confidentiality as medical records, except that:

(1) Supervisors and managers may be informed regarding restrictions on the work or duties that may be assigned to handicapped persons and regarding necessary accommodations;

(2) First aid and safety personnel may be informed, where appropriate, if the condition associated with the handicap might require emergency treatment; and

(3) Government officials investigating compliance with the Rehabilitation Act of 1973 shall be provided relevant information upon request.

§4.126 General requirement concerning program accessibility.

No qualified handicapped person shall, because a recipient's facilities are inaccessible to or unusable by handicapped persons, be denied the benefits of, be excluded from participation in, or otherwise be subjected to discrimination under any program or activity that receives or benefits from Federal financial assistance.

§4.127 Existing facilities.

(a) *Program accessibility.* A recipient shall operate each program or activity so that the program or activity, when viewed in its entirety, is readily accessible to and usable by handicapped persons. This paragraph does not necessarily require a recipient to make each of its existing facilities or every part of an existing facility accessible to and usable by handicapped persons.

(b) *Methods.* A recipient may comply with the requirements of paragraph (a) of this section through such means as redesign of equipment, reassignment of classes or other services to accessible buildings, assignment of aids to beneficiaries, home visits, delivery of health, welfare or other social services at alternate accessible sites, alteration of existing facilities and construction of new facilities in conformance with the requirements of § 4.128 or any other methods that result in making its program or activity accessible to and usable by handicapped persons. A recipient is not required to make structural changes in existing facilities where other methods are effective in achieving compliance with paragraph (a) of this section. In choosing among available methods for meeting the requirement of paragraph (a) of this section, a recipient shall give priority to those methods that offer programs and activities to handicapped persons in the most integrated setting appropriate.

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(c) *Time period.* A recipient shall comply with the requirement of paragraph (a) of this section within 60 days of the effective date of this subpart except that where structural changes in facilities are necessary, the changes are to be made within three years of the effective date of this subpart, but in any event, as expeditiously as possible.

(d) *Transition plan.* In the event that structural changes to facilities are necessary to meet the requirement of paragraph (a) of this section, a recipient shall develop, within 6 months of the effective date of this subpart, a transition plan setting forth the steps necessary to complete the changes. The plan is to be developed with the assistance of interested persons, including handicapped persons or organizations representing handicapped persons, and the plan is to meet with the approval of the NRC. A copy of the transition plan is to be made available for public inspection. At a minimum, the plan is to:

(1) Identify physical obstacles in the recipient's facilities that limit the accessibility and usability of its program or activity to handicapped persons;

(2) Describe in detail the methods that will be used to make the facilities accessible to and usable by handicapped persons;

(3) Specify the schedule for taking the steps necessary to achieve full program accessibility and, if the time period or the transition plan is longer than 1 year, identify steps that will be taken during each year of the transition period; and

(4) Indicate the person responsible for implementation of the plan.

(e) *Notice.* The recipient shall adopt and implement procedures to ensure that interested persons, including persons with impaired vision or hearing, can obtain information concerning the existence and location of services, activities, and facilities that are accessible to, and usable by, handicapped persons.

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§4.128 New construction.

(a) New facilities shall be designed and constructed to be readily accessible to and usable by handicapped persons. Alterations to existing facilities shall, to the maximum extent feasible, be designed and constructed to be readily accessible to and usable by handicapped persons.

(b) Design, construction, or alteration of facilities in conformance with the "American National Standard Specifications for Making Buildings and Facilities Accessible to, and Usable by, the Physically Handicapped," published by the American National Standards Institute, Inc. (ANSI A117.1-1961(R1971)), which is incorporated by reference in this subpart, shall constitute compliance with paragraph (a) of this section. Departures from particular requirements of those standards by the use of other methods shall be permitted when it is clearly evident that equivalent access to and use of the facility or part of the facility is thereby provided.

Enforcement

§4.231 Responsibility of applicants and recipients.

(a) *Assurances.* An applicant for Federal financial assistance for a program or activity to which this subpart applies shall submit an assurance, on a form specified by the responsible NRC official, that the program will be operated in compliance with the subpart. An applicant may incorporate these assurances by reference in subsequent applications to the NRC.

(b) *Duration of obligation.* The assurance will obligate the recipient for the period during which Federal financial assistance is extended.

(c) *Remedial action.* (1) If the responsible NRC official finds that a recipient has discriminated against persons on the basis of handicap in violation of section 504 or this subpart, the recipient shall take such remedial action as the responsible NRC official deems necessary to overcome the effect of the discrimination.

(2) Where a recipient is found to have discriminated against persons on the basis of handicap in violation of section 504 or this subpart and where another recipient exercises control over the recipient that has discriminated, the responsible NRC official, where appropriate, may require either or both recipients to take remedial action.

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(3) The responsible NRC official may, where necessary to overcome the effects of discrimination in violation of section 504 or this subpart, require a recipient to take remedial action (i) with respect to handicapped persons who are no longer participants in the recipient's program but who were participants in the program when such discrimination occurred or (ii) with respect to handicapped persons who would have been participants in the program had the discrimination not occurred

(d) *Voluntary action.* A recipient may take steps, in addition to any action that is required by this subpart, to overcome the effects of conditions that resulted in limited participation in the recipient's program or activity by qualified handicapped persons.

(e) *Self-evaluation.* (1) A recipient shall as soon as practicable:

(i) Evaluate, with the assistance of interested persons, including handicapped persons or organizations representing handicapped persons, its current policies and practices and the effects thereof that do not or may not meet the requirements of this subpart;

(ii) Modify, after consultation with interested persons, including handicapped persons or organizations representing handicapped persons, any policies and practices that do not meet the requirements of this subpart; and

(iii) Take, after consultation with interested persons, including handicapped persons or organizations representing handicapped persons, appropriate remedial steps to eliminate the effects of any discrimination that resulted from adherence to those policies and practices.

(2) A recipient shall, for at least three years following completion of the evaluation required under paragraph (e)(1) of this section, maintain on file, make available for public inspection, and provide to the responsible NRC official upon request:

(i) A list of the interested persons consulted, (ii) a description of areas examined and any problems identified, and (iii) a description of any modifications made and of any remedial steps taken.

(f) Designation of responsible employee. A recipient shall designate at least one person to coordinate its efforts to comply with this subpart.

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§ 4.232 Notice.

(a) A recipient shall take appropriate initial and continuing steps to notify participants, beneficiaries, applicants, and employees, including those with impaired vision or hearing, and unions or professional organizations holding collective bargaining or professional agreements with the recipient that it does not discriminate on the basis of handicap in violation of section 504 and this subpart. The notification shall state, where appropriate, that the recipient does not discriminate in admission or access to, or treatment or employment in, its programs and activities. The notification shall also include an identification of the responsible employee designated pursuant to § 4.231 (f). A present recipient shall make the initial notification required by this paragraph within 90 days of the effective date of this subpart. Methods of initial and continuing notification may include the posting of notices, publication in newspapers and magazines, placement of notices in recipients' publications, and distribution of memoranda or other written communications.

(b) If a recipient publishes or uses recruitment materials or publications containing general information that it makes available to participants, beneficiaries, applicants, or employees, it shall include in those materials or publications a statement of the policy described in paragraph (a) of this section. A recipient may meet the requirement of this paragraph either by including appropriate inserts in existing materials and publications or by revising and reprinting the materials and publications.

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§ 4.233 Enforcement procedures.

The enforcement and hearing procedures set forth in §§ 4.41–4.75 of Subpart A with respect to discrimination based on sex, race, color or national origin shall be used for the enforcement of the regulations in subpart B with respect to discrimination based on handicap.

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APPENDIX A—FEDERAL FINANCIAL ASSISTANCE TO WHICH THIS PART APPLIES [1]

(a) *Conferences on regulatory programs.* Agreements for financial assistance to State officials, without full-cost recovery, for visits to NRC facilities and offices or to other locations to confer on regulatory programs and related matters.

(b) *Orientation and instruction.* Agreements for assistance to State and local officials, without full-cost recovery, to receive orientation and on-the-job instruction at NRC facilities and offices.

(c) *Courses in fundamentals of radiation.* Agreements for the conduct of courses for State and local employees, without full-cost recovery, in fundamentals of radiation and radiation protection.

(d) *Participation in meetings and conferences.* Agreements for participation, without full-cost recovery, in meetings, conferences, workshops, and symposia to assist scientific, professional or educational institutions or groups.

45 FR 14533

(e) The Uranium Mill Tailings Radiation Control Act of 1978, section 207, Pub. L. 95–604, 92 Stat. 3033, authorizes grants to eligible Agreement States to aid in the development of state regulatory programs to implement those provisions of the Act which amended section 274 of the Atomic Energy Act of 1954, as amended.

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[1] Categories of assistance may be added to Appendix A from time to time by notice published in the FEDERAL REGISTER. This part shall be deemed to apply to all grants, loans or contracts entered into under any such category of assistance on or after the effective date of the inclusion of the category of assistance in Appendix A.

UNITED STATES NUCLEAR REGULATORY COMMISSION

RULES and REGULATIONS

TITLE 10, CHAPTER 1, CODE OF FEDERAL REGULATIONS—ENERGY

PART 4

NONDISCRIMINATION IN FEDERALLY ASSISTED COMMISSION PROGRAMS

PROPOSED RULE MAKING

46 FR 46582
Published 9/21/81

Comments must be received on or before November 20, 1981. Comments received after November 20, 1981 will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

10 CFR Part 4

Nondiscrimination on Basis of Age in Federally Assisted Commission Programs

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission is considering an amendment to its regulations which would implement the provisions of the Age Discrimination Act of 1975, as amended. The proposed amendment would make it unlawful for any recipient of Federal financial assistance to discriminate on the basis of age in programs or activities receiving Federal financial assistance. The Act also contains certain exceptions that permit, under limited circumstances, continued use of age distinctions or factors other than age that may have a disproportionate effect on the basis of age. The Act applies to persons of all ages.

DATES: Comments must be received on or before November 20, 1981. Comments received after November 20, 1981 will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

ADDRESSES: Written comments or suggestions for consideration in connection with the proposed amendments should be submitted to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC. 20555, Attention: Docketing and Service Branch. Copies of documents received may be examined at the Commission's Public Document Room at 1717 H Street, N.W., Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Mr. Hudson B. Ragan, Office of the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (Phone 301–492–8668).

SUPPLEMENTARY INFORMATION: Section 6102 of the Age Discrimination Act of 1975, as amended, provides in part that "no person in the United States shall, on the basis of age, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any program or activity receiving Federal financial assistance." The Act directs that all Federal agencies empowered to provide Federal financial assistance issue rules, regulations, and directives consistent with standards and procedures established by the Secretary of Health, Education and Welfare, now the Secretary of Health and Human Services (HHS). The standards and procedures established by the Secretary of HHS have been published as final general regulations in 45 CFR Part 90, 44 FR 33768 (1979). Differences in language between the proposed rule and the HHS general regulations are for the sake of clarity and are not intended to constitute substantive differences. The HHS general regulations are also referred to as the HHS government-wide regulations.

The proposed amendments would be added to 10 CFR Part 4 as Subpart C. The General Provisions, §§ 4.1 through 4.4, and Appendix A which identifies the NRC programs of financial assistance to which Part 4 applies, would be applicable to Subpart C. Subpart C is devoted exclusively to prohibiting discrimination on the basis of age in programs or activities which receive Federal financial assistance.

Sections 4.2 and 4.3(d) of the General Provisions have been amended to more closely conform to language used in the HHS government-wide regulations defining federal financial assistance. The revised language describes the coverage of Part 4 more specifically.

The Act, as implemented by these regulations, generally covers all programs and activities which receive Federal financial assistance. However, the Act and these regulations do not apply to any age distinction "established under authority of any law" which provides benefits or establishes criteria for participation on the basis of age or in age related terms (§ 4.302(b)). Thus, age distinctions which are "established under authority of any law" may continue in use. By the terms of § 4.302(b) "any law" refers to Federal statutes, state statutes, or local statutes adopted by elected, general purpose legislative bodies.

The Act also excludes from its coverage most employment practices, except for programs funded under the public service employment titles of the Comprehensive Employment and Training Act (CETA). These regulations do cover any program or activity which is both a program of Federal financial assistance and provides employment such as the College Work Study Program (42 U.S.C. 2751, *et seq.*) and the Work Incentive Program (42 U.S.C. 630, *et seq.*). The Age Discrimination in Employment Act (ADEA) which is administered by the Equal Employment Opportunity Commission (EEOC), continues to be the Federal statute that prohibits employment discrimination for persons between the ages of 40 and 70. Individuals in this age range who experience employment discrimination, other than in CETA public service employment programs, must look to the ADEA for relief, not to the Age Discrimination Act.

NRC Assistance Programs

The NRC currently provides assistance in the form of training programs for state personnel. The training is performed pursuant to section 274 of the Atomic Energy Act of 1954, as amended, which provides for state assumption of certain areas of NRC regulatory activity. This Agreement States Program is designed to improve the state employees' technical and administrative skills as well as develop an understanding and ability to apply regulatory concepts and procedures.

In addition to the Agreement States Program, the NRC has recently been entering into assistance relationships (grants and certain types of cooperative agreements) with a variety of eligible recipients for projects related to nuclear safety assessment. The use of these assistance instruments is designed to increase the flexibility available to NRC staff in stimulating research and information exchange in technical areas directly related to their regulatory responsibilities. Paragraph (e) of Appendix A is being revised to include this current program. Reference in paragraph (e) of Appendix A to the Uranium Mill Tailings Radiation Control Act of 1978, section 207, Pub. L. 95–604, 92 Stat. 3003, authorizing grants to eligible Agreement States to aid in the development of state regulatory programs, is being deleted since the authority for that program is no longer in effect.

NRC Interim Procedures

The HHS Age Discrimination Task Force has requested agencies who have not published final regulations to include in the publication of proposed regulations pertinent information regarding interim procedures to be followed in the filing and handling of complaints. Recipients and beneficiaries under all programs receiving Federal financial assistance from the NRC are on notice that complaints may be filed alleging acts of age discrimination occurring on or after July 1, 1979. Complaints concerning recipients and beneficiaries of Federal financial assistance from NRC should be addressed to: Director, Office of Equal Employment Opportunity, Nuclear Regulatory Commission, Washington, D.C. 10555.

NRC will screen all complaints and refer those deemed sufficient under the Act and HHS's general regulations (45 CFR Part 90) to the Federal Mediation and Conciliation Service (FMCS) for mediation. The FMCS began mediating complaints on November 1, 1979.

The Act states that a complainant may file a civil action 180 days from the date the complaint was filed if the agency has taken no action, or upon the date the agency makes a determination in favor of the recipient. For purposes of exhaustion of administrative remedies within NRC, the 180 day period will run from the date the complaint is filed with NRC. In cases where NRC has taken no action on a complaint and 180 days have passed, the complainant has the right to file a civil action in a United States District Court for the district in which the recipient is located or transacts business.

Regulatory Flexibility Statement

In accordance with sec. 605(b) of the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission hereby certifies that this rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. Pursuant to the provisions of the Age Discrimination Act of 1975, as amended, the proposed rule conditions the granting of Federal financial assistance by the NRC upon the basis that the recipient shall not discriminate because of age in programs sponsored by the NRC. Moreover, since there are no additional data collection or recordkeeping requirements necessary for compliance, the proposed rule, if implemented, will not result in imposing an economic burden on any recipient, including small entities.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and section 553 of Title 5 of the United States Code, notice is hereby given that adoption of the following amendments to 10 CFR Part 4 is contemplated.

1. In 10CFR Part 4 the table of contents and citation of authority are revised to read as follows:

PART 4—NONDISCRIMINATION IN FEDERALLY ASSISTED COMMISSION PROGRAMS

General Provisions

Sec.
4.1 Purpose and scope.
4.1a Subparts.
4.2 Application of this part.
4.3 Definitions.
4.4 Communications and reports.

Subpart A—Regulations Implementing Title VI of the Civil Rights Act of 1964 and Title IV of the Energy Reorganization Act of 1974

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4.11 General prohibition.
4.12 Specific discriminatory actions prohibited.
4.13 Employment practices.
4.14 Medical emergencies.

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4.21 General requirements.
4.22 Continuing State programs.
4.24 Assurances from institutions.

Compliance Information

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4.33 Access to sources of information.
4.34 Information to beneficiaries and participants.

Conduct of Investigations

4.41 Periodic compliance reviews.
4.42 Complaints.
4.43 Investigations.
4.44 Resolution of matters.
4.45 Intimidatory of retaliatory acts prohibited.

Means of Effecting Compliance

4.46 Means available.
4.47 Noncompliance with § 4.21.
4.48 Termination of our refusal to grant or to continue Federal financial assistance.
4.49 Other means anthorized by law.

Opportunity for Hearing

4.51 Notice of Opportunity for hearing.

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4.73 Rulings required.
4.74 Content of orders.
4.75 Post termination proceedings.

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4.81 Judicial review.

Effect on Other Regulations; Forms and Instructions

4.91 Effect on other regulations.
4.92 Forms and instructions.
4.93 Supervision and coordination.

Subpart B—Regulations Implementing Section 504 of the Rehabilitation Act of 1973, as Amended

4.101 Definitions.

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4.121 General prohibitions against discrimination.
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4.123 Reasonable accommodiation.
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4.126 General requirement concerning program accessiblity.
4.127 Existing facilities.
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Enforcement

4.231 Responsiblity of applicants and recipients.
4.232 Notice.
4.233 Enforcement procedures.

Subpart C—Regulations Implementing the Age Discrimination Act of 1975, as Amended

General

4.301 Purpose and scope.
4.302 Application of this subpart.
4.303 Definitions.

Standards for Determining Age Discrimination

4.311 Rules against age discrimination.
4.312 Definitions of "normal operation" and "statutory objective".
4.313 Exceptions to the rules against age discrimination. Normal operation or statutory objective of any program or activity.
4.314 Exceptions to the rules against age discrimination. Reasonable factors other than age.
4.315 Burden of proof.

Duties of NRC Recipients

4.321 Assurance of compliance.
4.322 Written notice, technical assistance, and educational materials.
4.324 Information requirements.

Investigation, Conciliation and Enforcement Procedures

4.331 Compliance reviews.
4.332 Complaints.
4.333 Mediation.
4.334 Investigation.

4.335 Prohibition against intimidation or retaliation.
4.336 Compliance procedure.
4.337 Hearings, decisions, post-termination proceedings.
4.338 Remedial and affirmative action by recipients.
4.339 Alternate funds disbursal procedure.
4.340 Exhaustion of administrative remedies.
4.341 Reports.

Appendix—A Federal Financial Assistance to Which This Part Applies.

Authority: Sec. 161, Pub. L 83–703, 68 Stat. 948, as amended (42 U.S.C. 2201); sec. 274, Pub. L. 86–373, 73 Stat. 688, as amended (42 U.S.C. 2021); sec. 207, Pub. L. 95–604, 92 Stat. 3033, sec. 201, Pub. L. 93–438, 88 Stat. 1242 (42 U.S.C. 5841); Subpart A also issued under secs. 602–605, Pub. L. 88–352, 78 Stat. 252, 253 (42 U.S.C. 2000d–1–2000d–4) and sec. 401, Pub. L. 93–438, 88 Stat. 1254 (42 U.S.C. 5891); Subpart B also issued under sec. 504, Pub. L. 93–112, 87 Stat. 394 (29 U.S.C. 794); sec. 111(a), Pub. L. 93–516, 88 Stat. 1619 (29 U.S.C. 706), sec. 119, Pub. L. 95–602, 92 Stat. 2982 (29 U.S.C. 794); and sec. 122, Pub. L. 95–602, 92 Stat. 2984 (29 U.S.C. 706 (6)); Subpart C also issued under Title III of Pub. L. 94–135, 89 Stat. 728, as amended (42 U.S.C. 6101).

2. Sections 4.1, 4.1a, 4.2 and 4.3(d) are revised to read as follows:

General Provisions

§ 4.1 Purpose and scope.

The regulations in this part implement: (a) the provisions of Title VI of the Civil Rights Act of 1964, Pub. L. 88–352, and Title IV of the Energy Reorganization Act of 1974, Pub. L. 93–438, which relate to nondiscrimination with respect to race, color, national origin or sex in any program or activity receiving Federal financial assistance from NRC; (b) the provisions of section 504 of the Rehabilitation Act of 1973, as amended, Pub. L. 93–112, Pub. L. 95–602, which relates to nondiscrimination with respect to the handicapped in any program or activity receiving Federal financial assistance; and (c) the provisions of the Age Discrimination Act of 1975, as amended Pub. L. 94–135, Pub. L. 95–478, which relate to nondiscrimination on the basis of age in any program or activity receiving Federal financial assistance.

§ 4.1a Subparts.

Subpart A sets forth rules applicable to Title VI of the Civil Rights Act of 1964 and Title IV of the Energy Reorganization Act of 1974. (The Acts are collectively referred to in Subpart A as the "Act".) Subpart B sets forth rules applicable specifically to matters pertaining to section 504 of the Rehabilitation Act of 1973, as amended. Subpart C set forth rules pertaining to the provisions of the Age Discrimination Act of 1975 as amended, Pub. L. 94–135, Pub. L. 95–478, which relate to nondiscrimination on the basis of age in any program or activity receiving Federal financial assistance.

§ 4.2 Application of this part.

This part applies to any program for which Federal financial assistance is authorized under a law administered by NCR. The programs to which this part applies are listed in Appendix A of this part; Appendix A may be revised from time to time by notice published in the Federal Register. This part applies to money paid, property transferred, or other Federal assistance extended under any program or activity, by way of grant, entitlement, cooperative agreement, loan, or contract or other agreement by NRC, or an authorized contractor or subcontractor of NRC, the terms of which require compliance with this part. If any statutes implemented by this part are otherwise applicable, the failure to list a program in Appendix A does not mean the program is not covered by this part. This part does not apply to:

(a) Contracts of insurance or guaranty; or

(b) Procurement contracts; or

(c) Employment practices under any program or activity except as provided in §§ 4.13, 4.122 and 4.302.

§ 4.3 Definitions.

* * * * *

(d) "Federal financial assistance" means any grant, entitlement, loan, cooperative agreement, contract (other than a procurement contract or a contract of insurance or guaranty), or any other arrangement by which NRC provides or otherwise makes available assistance in the form of:

(1) Funds;

(2) Services of Federal personnel or other personnel at Federal expense; or

(3) Real and personal property or any interest in or use of property, including—

(i) Transfers or leases of property for less than fair market value or for reduced consideration;

(ii) Proceeds from a subsequent transfer or lease of property if the Federal share of its fair market value is not returned to the Federal Government; and the

(iii) Sale and lease of, and the permission to use (other than on casual or transient basis) Federal property or any interest in such property without consideration or at a nominal consideration, or at a consideration which is reduced for the purpose of assisting the recipient, or in recognition of the public interest to be served by such sale or lease to the recipient.

* * * * *

Appendix A [Relocated]

3. Appendix A, which follows § 4.233, is relocated to follow § 4.341.

4. Immediately following § 4.233, a new subpart C is added to read as follows:

Subpart C—Regulations Implementing the Age Discrimination Act of 1975, as amended.

General

§ 4.301 Purpose and scope.

The purpose of this subpart is to set forth NRC policies and procedures under the Age Discrimination Act of 1975 which prohibits discrimination on the basis of age in programs or activities receiving Federal financial assistance.

§ 4.302 Application of this subpart.

(a) The Age Discrimination Act of 1975 and these regulations apply to any program or activity receiving Federal financial assistance from NRC.

(b) The Age Discrimination Act of 1975 and these regulations do not apply to:

(1) An age distinction contained in that part of a Federal, state or local statute or ordinance adopted by an elected, general purpose legislative body which:

(i) Provides any benefits or assistance to persons based on age; or

(ii) Establishes criteria for participation in age-related terms; or

(iii) Describes intended beneficiaries or target groups in age-related terms.

(2) Any employment practice of any employer, employment agency, labor organization, or any labor-management joint apprenticeship training program, except for any program or activity receiving Federal financial assistance for public service employment under the Comprehensive Employment and Training Act of 1974 (CETA) (29 U.S.C. 801 *et seq.*).

§ 4.303 Definitions.

As used in this subpart:

(a) "Act" means the Age Discrimination Act of 1975, as amended, (Title III of Pub. L. 94–135).

(b) "Action" means any act, activity, policy, rule, standard, or method of administration; or the use of any policy, rule, standard, or method of administration.

(c) "Age" means how old a person is, or the number of elapsed years from the date of a person's birth.

(d) "Age distinction" means any action using age or an age-related term.

(e) "Age-related term" means a word or words which necessarily imply a particular age or range of ages (for example, "children," "adult," "older persons," but not "student").

(f) "Subrecipient" means any of the entities in the definition of "recipient" to which a recipient extends or passes on Federal financial assistance. A subrecipient is generally regarded as a recipient of Federal financial assistance and has all the duties of a recipient in these regulations.

Standards for Determining Age Discrimination

§ 4.311 Rules against age discrimination.

The rules stated in this section are limited by the exceptions contained in §§ 4.313 and 4.314 of this subpart.

(a) *General rule:* No person in the United States shall, on the basis of age, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any program or activity receiving Federal financial assistance.

(b) *Specific rules:* A recipient may not, in any program or activity receiving Federal financial assistance, directly or through contractual, licensing, or other arrangements use age distinctions or take any other actions which have the effect, on the basis of age, of:

(1) Excluding individuals from, denying them the benefits of, or subjecting them to discrimination under, a program or activity receiving Federal financial assistance, or

(2) Denying or limiting individuals in their opportunity to participate in any program or activity receiving Federal financial assistance.

(c) The specific forms of age discrimination listed in paragraph (b) of this section do not necessarily constitute a complete list.

§ 4.312 Definitions of "normal operation" and "statutory objective".

For purposes of §§ 4.313 and 4.314, the terms "normal operation" and "statutory objective" have the following meaning:

(a) "Normal operation" means the operation of a program or activity without significant changes that would impair its ability to meet its objectives.

(b) "Statutory objective" means any purpose of a program or activity expressly stated in any Federal statute, state statute, or local statute or ordinance adopted by an elected, general purpose legislative body.

§ 4.313 Exceptions to the rules against age discrimination. Normal operation or statutory objective of any program or activity.

A recipient is permitted to take an action, otherwise prohibited by § 4.311, if the action reasonably takes into account age as a factor necessary to the normal operation or the achievement of any statutory objective of a program or activity. An action reasonably takes into account age as a factor necessary to the normal operation or the achievement of any statutory objective of a program or activity, if:

(a) Age is used as a measure or approximation of one or more other characteristics; and

(b) The other characteristic(s) must be measured or approximated in order for the normal operation of the program of activity to continue, or to achieve any statutory objective of the program or activity; and

(c) The other characteristic(s) can be reasonably measured or approximated by the use of age; and

(d) The other characteristic(s) are impractical to measure directly on an individual basis.

§ 4.314 Exceptions to the rules against age discrimination. Reasonable factors other than age.

A recipient is permitted to take an action otherwise prohibited by § 4.311 which is based on a factor other than age, even though that action may have a disproportionate effect on persons of different ages. An action may be based on a factor other than age only if the factor bears a direct and substantial relationship to the normal operation of the program or activity or to the achievement of a statutory objective.

§ 4.315 Burden of proof.

The burden of proving that an age distinction or other action falls within the exceptions outlined in §§ 4.313 and 4.314 is on the recipient of Federal financial assistance.

Duties of NRC Recipients

§ 4.321 Assurance of compliance.

Each NRC recipient has primary responsibility to ensure that its programs and activities are in compliance with the Act and these regulations. Each recipient will sign an assurance of compliance that its programs and activities will be conducted in compliance with all the requirements imposed by the Act and these regulations. A recipient also has responsibility to maintain records, provide information, and to afford access to its records to NRC, to the extent required to determine whether it is in compliance with the Act and these regulations.

§ 4.322 Written notice, technical assistance, and educational materials.

(a) NRC will provide written notice to each recipient of its obligations under the Act and these regulations, including its obligation under paragraph (b) of this section.

(b) Where a recipient makes available Federal financial assistance from NRC to a subrecipient, the recipient shall provide the subrecipient written notice of the subrecipient's obligations under the Act and these regulations.

(c) NRC will provide technical assistance, where necessary, to recipients to aid them in complying with the Act and these regulations.

(d) NRC will make available educational materials which set forth the rights and obligations of recipients and beneficiaries under the Act and these regulations.

§ 4.324 Information requirements.

Each recipient shall:

(a) Make available upon request to NRC information necessary to determine whether the recipient is complying with the Act and these regulations.

(b) Permit reasonable access by NRC to the recipient's books, records, accounts, facilities and other sources of information to the extent necessary to determine whether the recipient is in compliance with the Act and these regulations.

Investigation, Conciliation, and Enforcement Procedures

§ 4.331 Compliance reviews.

(a) NRC may conduct compliance reviews and preaward reviews of recipients or use other similar procedures that will permit it to investigate and correct violations of the Act and these regulations. NRC may conduct these reviews even in the absence of a complaint against a recipient. The review may be as comprehensive as necessary to determine whether a violation of these regulations has occurred.

(b) If a compliance review or preaward review indicates a violation of the Act or these regulations, NRC will attempt to achieve voluntary compliance with the Act. If voluntary compliance cannot be achieved, NRC will arrange for enforcement as described in § 4.336.

§ 4.332 Complaints.

(a) Any person, individually or as a member of a class or on behalf of others, may file a complaint with NRC, alleging discrimination prohibited by the Act or these regulations based on an action occurring on or after July 1, 1979. A complainant shall file a complaint within 180 days from the date the complainant first had knowledge of the alleged act of discrimination. However, for good cause shown, NRC may extend this time limit.

(b) NRC will attempt to facilitate the filing of complaints wherever possible, including taking the following measures:

(1) Accepting a complaint as sufficient for further processing which: (i) is made in writing; (ii) alleges a violation of the Act; (iii) identifies the parties involved and the date the complainant first had knowledge of the alleged violation; (iv) describes generally the action or practice complained of; and (v) is signed by the complainant.

(2) Freely permitting a complainant to add information to the complaint to meet the requirements of a sufficient complaint.

(3) Notifying the complainant and the recipient of their rights and obligations under the complaint procedure, including the right to have a representative at all stages of the complaint procedures.

(4) Notifying the complainant and the recipient (or their representatives) of their right to contact NRC for information and assistance regarding the complaint resolution process.

(c) Each recipient and complainant shall participate actively in efforts toward speedy resolution of the complaint.

(d) NRC will return to the complainant any complaint outside the jurisdiction of these regulations, and will state the reason(s) why it is outside the jurisdiction of these regulations.

§ 4.333 Mediation.

(a) *Referral of complaints for mediation.* NRC will refer to a mediation agency designated by the Secretary of the Department of Health and Human Services all complaints that:

(1) Fall within the jurisdiction of the Act and these regulations; and

(2) Contain all information necessary for further processing.

(b) Both the complainant and the recipient shall participate in the mediation process to the extent necessary to reach an agreement or make an informed judgment that an agreement is not possible. There must be at least one meeting with the mediator before NRC will accept a judgment that an agreement is not possible. However, the recipient and the complainant need not meet with the mediator at the same time.

(c) If the complainant and the recipient reach an agreement, the mediator shall prepare a written statement of the agreement and have the complainant and recipient sign it. The mediator shall send a copy of the agreement to NRC. NRC will take no further action on the complaint unless the complainant or recipient fails to comply with the agreement.

(d) The mediator shall protect the confidentiality of all information obtained in the course of the mediation process. No mediator shall testify in any adjudicative proceeding, produce any document, or otherwise disclose any information obtained in the course of the mediation process without prior approval of the head of the agency appointing the mediator.

(e) NRC will use the mediation process for a maximum of 60 days after receiving a complaint. Mediation ends if:

(1) 60 days elapse from the time NRC receives the complaint; or

(2) Prior to the end of that 60 day period, the mediator determines an agreement is reached; or

(3) Prior to the end of that 60 day period, the mediator determines that an agreement cannot be reached.

(f) The mediator shall return unresolved complaints to NRC.

§ 4.334 Investigation.

(a) *Informal investigation.*

(1) NRC will investigate complaints that are unresolved after mediation or are reopened because of a violation of a mediation agreement.

(2) As part of the initial investigation, NRC will use informal fact finding methods, including joint or separate discussions with the complainant and recipient to establish the facts, and, if possible, settle the complaint on terms that are mutually agreeable to the parties. NRC may seek the assistance of any involved State program agency.

(3) NRC will put any agreement in writing and have it signed by the parties and an authorized official at NRC.

(4) The settlement shall not affect the operation of any other enforcement effort of NRC, including compliance reviews and investigation of other complaints which may involve the recipient.

(5) Settlement of a complaint under this section will not constitute a finding of discrimination by the NRC against a recipient or an admission of discrimination by the recipient.

(b) *Formal investigation.* If NRC cannot resolve the complaint through informal investigation, it will begin to develop formal findings through further investigation of the complaint. If the investigation indicates a violation of these regulations, NRC will attempt to obtain voluntary compliance. If NRC cannot obtain voluntary compliance, it will begin enforcement as described in § 4.336.

§ 4.335 Prohibition against intimidation or retaliation.

A recipient may not engage in acts of intimidation or retaliation against any person who:

(a) Attempts to assert a right protected by the Act or these regulations; or

(b) Cooperates in any mediation, investigation, hearing, or other part of NRC's investigation, conciliation, and enforcement process.

§ 4.336 Compliance procedure.

(a) NRC may enforce the Act and these regulations through:

(1) Termination of a recipient's Federal financial assistance from NRC under the program or activity involved where the recipient has violated the Act or these regulations. The determination of the recipients's violation may be made only after a recipient has had an opportunity for a hearing on the record before an administrative law judge. Therefore, cases which are settled in mediation, or prior to a hearing, will not involve termination of a recipient's Federal financial assistance from NRC.

(2) Any other means authorized by law including but not limited to:

(i) Referral to the Department of Justice for proceedings to enforce any rights of the United States or obligations of the recipient created by the Act or these regulations.

(ii) Use of any requirement of or referral to any Federal, State, or local government agency that will have the effect of correcting a violation of the Act or these regulations.

(b) NRC will limit any termination under § 4.336(a)(1) to the particular recipient and particular program or activity NRC finds in violation of the Act or these regulations. NRC will not base any part of a termination on a finding with respect to any program or activity of the recipient which does not receive Federal financial assistance from NRC.

(c) NRC will take no action under paragraph (a) until:

(1) The Commission, or designee, has advised the recipient of its failure to comply with the Act or these regulations and has determined that voluntary compliance cannot be obtained.

(2) Thirty days have elapsed after the Commission, or designee, has sent a written report of the circumstances and grounds of the action to the committees of the Congress having legislative jurisdiction over the Federal program or activity involved. A report will be filed whenever any action is taken under paragraph (a) of this section.

(d) NRC also may defer granting new Federal financial assistance to a recipient when termination proceedings under § 4.336(a)(1) are initiated.

(1) New Federal financial assistance includes all assistance for which NRC requires an application or approval, including renewal or continuation of existing activities, or authorization of new activities, during the deferral period. New Federal financial assistance does not include increases in funding as a result of changed computation of formula awards or assistance approved prior to the beginning of termination proceedings under § 4.336(a)(1).

(2) NRC will not begin a deferral until the recipient has received a notice of an opportunity for a hearing under § 4.336(a)(1). NRC will not continue a deferral for more than 60 days unless a hearing has begun within that time or the time for beginning the hearing has been extended by mutual consent of the recipient and NRC. NRC will not continue a deferral for more than 30 days after the close of the hearing, unless the hearing results in a finding against the recipient.

§ 4.337 Hearings, decisions, post-termination proceedings.

Certain NRC procedural provisions applicable to Title VI of the Civil Rights Act of 1964 apply to NRC enforcement of these regulations. They are §§ 4.61 through 4.64 and §§ 4.71 through 4.75.

§ 4.338 Remedial and affirmative action by recipients.

(a) Where NRC finds a recipient has discriminated on the basis of age, the recipient shall take any remedial action that NRC may require to overcome the effects of the discrimination. If another recipient exercises control over the recipient that has discriminated, NRC may require both recipients to take remedial action.

(b) Even in the absence of a finding of discrimination, a recipient may take affirmative action to overcome the effects of conditions that resulted in limited participation in the recipient's program or activity on the basis of age.

(c) If a recipient operating a program which serves the elderly or children in addition to persons of other ages provides special benefits to the elderly or to children the provision of those benefits shall be presumed to be voluntary affirmative action provided that it does not have the effect of excluding otherwise eligible persons from participation in the program.

§ 4.339 Alternate funds disbursal procedure.

(a) When NRC withholds funds from a recipient under these regulations, the Commission, or designee, may disburse the withheld funds directly to an alternate recipient: any public or nonprofit private organization or agency, or state or political subdivision of the state.

(b) Any alternative recipient will be required to demonstrate: (1) The ability to comply with these regulations; and (2) The ability to achieve the goals of the Federal statute authorizing the program or activity.

§ 4.340 Exhaustion of administrative remedies.

(a) A complainant may file a civil action following the exhaustion of administrative remedies under the Act. Administrative remedies are exhausted if:

(1) 180 days have elapsed since the complainant filed the complaint and NRC has made no finding with regard to the complaint; or

(2) NRC issues any finding in favor of the recipient.

(b) If NRC fails to make a finding within 180 days or issues a finding in favor of the recipient, NRC will:

(1) Promptly advise the complainant; and

(2) Advise the complainant of his or her right to bring a civil action under Section 305(e) of the Act for injunctive relief that will effect the purposes of the Act; and

(3) Inform the complainant:

(i) that the complainant may bring a civil action only in a United States district court for the district in which the recipient is found or transacts business;

(ii) That a complainant prevailing in a civil action has the right to be awarded the costs of the action, including reasonable attorney's fees, but that the complainant must demand these costs in the complaint;

(iii) That before commencing the action the complainant shall give 30 days' notice by registered mail to the Commission, the Secretary of the Department of Health and Human Services, the Attorney General of the United States, and the recipient;

(iv) That the notice must state: the alleged violation of the Act; the relief requested; the court in which the complainant is bringing the action; and whether or not attorney's fees are demanded in the event the complainant prevails; and

(v) That the complainant may not bring an action if the same alleged violation of the Act by the same recipient is the subject of a pending action in any court of the United States.

§ 4.341 Reports.

The NRC shall submit to the Secretary of Health and Human Services not later than December 31 of each year, a report which:

(a) Describes in detail the steps taken during the preceding fiscal year to carry out the Act; and

(b) Contains data on the frequency, type, and resolution of complaints and on any compliance reviews, sufficient to permit analysis of the agency's progress in reducing age discrimination in programs receiving Federal financial assistance from NRC; and

(c) Contains data directly relevant to the extent of any pattern or practice of age discrimination which NRC has identified in any programs receiving Federal financial assistance from NRC and to progress toward eliminating it; and

(d) Contains evaluative or interpretative information which NRC determines is useful in analyzing agency progress in reducing age discrimination in programs receiving Federal financial assistance from NRC; and

(e) Contains whatever other data the Secretary of HHS may require.

5. Paragraph (e) of Appendix A is revised to read as follows:

Appendix A—Federal Financial Assistance to which this Part Applies

* * * * *

(e) Research Support. Agreements for the financial support of basic and applied scientific research and for the exchange of scientific information.

Dated at Washington, D.C., this 15th day of September 1981.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

➢49 FR 34132
Published 8/28/84
Comment period expires 12/26/84.

10 CFR Part 4

Enforcement of Nondiscrimination on the Basis of Handicap in Federally Conducted Programs

AGENCIES: National Capital Planning Commission; National Commission for Employment Policy; Nuclear Regulatory Commission; National Credit Union Administration; Commodity Futures Trading Commission; Tennessee Valley Authority; Department of State; U.S. Information Agency; Inter-American Foundation; Japan-United States Friendship Commission; Navajo & Hopi Indian Relocation Commission; Occupational Safety and Health Review Commission; Pension Benefit Guaranty Corporation; Advisory Council on

Historic Preservation; Pennsylvania Avenue Development Corporation; Commission of Fine Arts; Committee for Purchase From the Blind and Other Severely Handicapped; General Services Administration; National Endowment for the Arts; Federal Maritime Commission; Interstate Commerce Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed regulation provides for the enforcement of section 504 of the Rehabilitation Act of 1973, as amended, which prohibits discrimination on the basis of handicap, as it applies to program or activities conducted by the agencies listed above.

DATES: To be assured of consideration, comments must be in writing and must be received on or before December 26, 1984. Comments should refer to specific sections in the regulation.

ADDRESSES: See individual agencies below.

FOR FURTHER INFORMATION CONTACT: See individual agencies below.

SUPPLEMENTARY INFORMATION:

Background

The purpose of this proposed rule is to provide for the enforcement of section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 794), as it applies to programs and activities conducted by the following agencies (hereinafter "the agencies"): National Capital Planning Commission, National Commission for Employment Policy, U.S. Nuclear Regulatory Commission, National Credit Union Administration, Commodity Futures Trading Commission, Tennessee Valley Authority, Unitled States Department of State, U.S. Information Agency, Inter-American Foundation, Japan-United States Friendship Commission, Navajo and Hopi Indian Relocation Commission, Occupational Safety and Health Review Commission, Pension Benefit Guaranty Corporation, Advisory Council of Historic Preservation, Pennsylvania Avenue Development Corporation, Commission of Find Arts, Committee for Purchase from the Blind and Other Severely Handicapped, General Services Administration, National Endowment for the Arts, Federal Maritime Commission, Interstate Commerce Commission. As amended by the Rehabilitation, Comprehensive Service, and Developmental Disabilities Amendments of 1978 (Sec. 119, Pub. L. 95–602, 92 Stat. 2982), section 504 of the Rehabilitation Act of 1973 states that:

> No otherwise qualified handicapped individual in the United States, * * * shall, solely by reason of his handicap, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance *or under any program or activity conducted by any Executive agency or the United States Postal Services. The head of each such agency shall promulgate such regulations a may be necessary to carry out the amendments to this section made by the Rehabilitation, Comprehensive Services, and Developmental Disabilities Act of 1978. Copies of any proposed regulation shall be submitted to appropriate authorizing committees of the Congress, and such regulation may take effect no earlier than the thirtieth day after the date on which such regulation is so submitted to such committees.*

(29 U.S.C. 794) (amendment italicized)

Because the agencies are required by this amendment to promulgate implementing regulations, and because the proposed standards and procedures to be established are the same for all of the agencies, the agencies are publishing this notice of proposed rulemaking jointly. The final rule adopted by each agency will be codified in that agency's portion of the Code of Federal Regulations as indicated in the information provided for individual agencies below. The agencies agreed to joint publication of the preamble and the text of the regulation in order to expedite its issuance and minimize costs in view of the identity in proposed standards among the agencies. If, following the public comment period, one or more of the agencies desires to promulgate a final regulation with different substantive provisions in order to account for its particular needs identified in response to public comments, it will, of course, do so.

The substantive nondiscrimination obligations of the agency, as set forth in this proposed rule, are identical, for the most part, to those established by Federal regulations for programs or activities receiving Federal financial assistance. *See* 28 CFR Part 41 (section 504 coordination regulation for federally assisted programs). This general parallelism is in accord with the intent expressed by supporters of the 1978 amendment in floor debate, including its sponsor, Rep. James M. Jeffords, that the Federal Government should have the same section 504 obligations as recipients of Federal financial assistance. 124. Cong. Rec. 13,901 (1978) (remarks of Rep. Jeffords); 124 Cong. Rec. E2668, E2670 (daily ed. May 17, 1978) *id.;* Cong. Rec. 13,897 (remarks of Rep. Brademas); *id.* at 38,552 (remarks of Rep. Sarasin).

This regulation has been reviewed by the Department of Justice. It is an adaptation of a prototype prepared by the Department of Justice under Executive Order 12250 (45 FR 72995, 3 CFR, 1980 Comp., p. 298) and distributed to Executive agencies.

This regulation has also been reviewed by the Equal Employment Opportunity Commission under Executive Order 12067 (43 FR 28967, 3 CFR, 1978 Comp., p. 206).

It is not a major rule within the meaning of Executive Order 12291 (46 FR 13193, 3 CFR, 1981 Comp., p. 127) and, therefore, a regulatory impact analysis has not been prepared.

This regulation does not have an impact on small entities. It is not, therefore, subject to the Regulatory Flexibility Act (5 U.S.C. 601–612).

Section-by-Section Analysis

Section —.101 Purpose.

Section —.101 states the purpose of the proposed rule, which is to effectuate section 119 of the Rehabilitation, Comprehensive Services, and Developmental Disabilities Amendments of 1978, which amended section 504 of the Rehabilitation Act of 1973 to prohibit discrimination on the basis of handicap in programs or activities conducted by Executive agencies or the United States Postal Service.

Section —.102 Application.

The proposed regulation applies to all programs or activities conducted by the agency.

Section —.103 Definitions.

"Assistant Attorney General." "Assistant Attorney General" refers to the Assistant Attorney General, Civil Rights Division, United States Department of Justice.

"Auxiliary aids." "Auxiliary aids" means services or devices that enable persons with impaired sensory, manual, or speaking skills to have an equal opportunity to participate in and enjoy the benefits of the agency's programs or activities. The definition provides examples of commonly used auxiliary aids. Although auxiliary aids are required explicitly only by § —.160(a)(1), they may also be necessary to meet other requirements of the regulation.

"Complete complaint." The definition of "complete complaint" enables the agency to determine the beginning of its obligations to investigate a complaint (*see* § —.170(d)).

"Facility." The definition of "facility" is similar to that in the section 504 coordination regulation for federally assisted programs, 28 CFR 41.3(f), except that the term "rolling stock or other conveyances" has been added and the phrase "or interest in such property" has been deleted to clarify its coverage. The phrase, "or interest in such property," is deleted, because the term "facility," as used in this regulation, refers to structures and not to intangible property rights. It should, however, be noted that the regulation applies to all programs and activities conducted by the agency regardless of whether the facility in which they are conducted is owned.

leased, or used on some other basis by the agency. The term "facility" is used in §§ —.149,—.150, and —.170(f).

"Handicapped person." The definition of "handicapped person" is identical to the definition appearing in the section 504 coordination regulation for federally assisted programs (28 CFR 41.31).

"Historic preservation programs," "Historic properties," and "Substantial impairment." These terms are defined in order to aid in the interpretation of § —.150 (a)(2) and (b)(2), which relate to accessibility of historic preservation programs.

"Qualified handicapped person." The definition of "qualified handicapped person" is a revised version of the definition appearing in the section 504 coordination regulation for federally assisted programs (28 CFR 41.32).

Paragraph (1) is an adaptation of existing definitions of "qualified handicapped person" for purposes of federally assisted preschool, elementary, and secondary education programs (*see, e.g.*, 45 CFR 84.3(k)(2)). It provides that a handicapped person is qualified for preschool, elementary, or secondary education programs conducted by the agency, if he or she is a member of a class of persons otherwise entitled by statute, regulation, or agency policy to recieve these services from the agency. In other words, a handicapped person is qualified if, considering all factors other than the handicapping condition, he or she is entitled to receive education services from the agency.

Paragraph (2) deviates from existing regulations for federally assisted programs because of intervening court decisions. It defines "qualified handicapped person" with regard to any program other than those covered by paragraph (1) under which a person is required to perform services or to achieve a level of accomplishment. In such programs a qualified handicapped person is one who can achieve the purpose of the program without modifications in the program that would result in a fundmental alteration in its nature. This definition reflects the decision of the Supreme Court in *Southeastern Community College* v. *Davis*, 442 U.S. 397 (1979). In that case, the Court ruled that a hearing-impaired applicant to a nursing school was not a "qualified handicapped person" because her hearing impairment would prevent her from participating in the clinical training portion of the program. The Court found that, if the program were modified so as to enable the respondent to participate (by exempting her from the clinical training requirements), "she would not receive even a rough equivalent of the training a nursing program normally gives." *Id.* at 410. It also found that "the purpose of [the] program was to train persons who could serve the nursing profession in all customary ways," *id.* at 413, and that the respondent would be unable, because of her hearing impairment, to perform some functions expected of a registered nurse. It therefore concluded that the school was not required by section 504 to make such modifications that would result in "a fundamental alteration in the nature of the program." *Id.* at 410.

We have incorporated the Court's language in the definition of "qulaified handicapped person" in order to make clear that such a person must be able to participate in the program offered by the agency. The agency is required to make modifications in order to enable a handicapped applicant to participate, but is not required to offer a program of a fundamentally different nature. The test is whether, with appropriate modifications, the applicant can achieve the purpose of the program offered; not whether the applicant could benefit or obtain results from some other program that the agency does not offer. Although the revised definition allows exclusion of some handicapped people from some programs, it requires that a handicapped person who is capable of achieving the purpose of the program must be accommodated, provided that the modifications do not fundamentally alter the nature of the program.

We encourage comment on paragraph (2). The language we have proposed comes directly from the Supreme Court's interpretation of section 504. However, so long as the definition of "qualified handicapped person" remains faithful to the statute and current case law, we are receptive to alternative language.

For programs or activities that do not fall under either of the first two paragraphs, paragraph (3) adopts the existing definition of "qualified handicapped person" with respect to services (28 CFR 41.32(b)) in the coordination regulation for programs receiving Federal financial assistance. Under this definition, a qualified handicapped person is a handicapped person who meets the essential eligibility requirements for participation in the program or activity.

"Section 504." This definition makes clear that, as used in this regulation, "section 504" applies only to programs or activities conducted by the agency and not to programs or activities to which it provides Federal financial assistance.

Section —.110 Self-evaluation.

The agency shall conduct a self-evaluation of its compliance with section 504 within one year of the effective date of this regulation. The process shall include consultation with interested persons, including consultation with handicapped persons or organizations representing handicapped persons. The Department of Justice is considering whether and to what degree the Federal Advisory Committee Act (5 U.S.C. app.) is applicable to the proposed consultation requirement. The self-evaluation requirement is present in the existing section 504 coordination regulation for programs or activities receiving Federal financial assistance (28 CFR 41.5(b)(2)). Experience has demonstrated the self-evaluation process to be a valuable means of establishing a working relationship with handicapped persons that promotes both effective and efficient implementation of section 504.

Section —.111 Notice.

Section —.111 requires the agency to disseminate sufficient information to employees, applicants, participants, beneficiaries, and other interested persons to apprise them of rights and protections afforded by section 504 and this regulation. Methods of providing this information include, for example, the publication of information in handbooks, manuals, and pamphlets that are distributed to the public to describe the agency's programs and activities; the display of informative posters in service centers and other public places; or the boradcast of information by television or radio.

Section—.130 General prohibitions against discrimination.

Section—.130 is an adaptation of the corresponding section of the section 504 coordination regulation for programs or activities receiving Federal financial assistance (28 CFR 41.51).

Paragraph (a) restates the nondiscrimination mandate of section 504. The remaining paragraphs in § —.130 establish the general principles for analyzing whether any particular action of the agency violates this mandate. These principles serve as the analytical foundation for the remaining sections of the regulation. Whenever the agency has violated a provision in any of the subsequent sections, it has also violated one of the general prohibitions found in § —.130. When there is no applicable subsequent provision, the general prohibitions stated in this section apply.

Paragraph (b) prohibits overt denials of equal treatment of handicapped persons. The agency may not refuse to provide a handicapped person with an equal opportunity to participate in or benefit from its program simply because the person is handicapped. Such blatantly exclusionary practices often result from the use of irrebuttable presumptions that absolutely exclude certain classes of disable persons (*e.g.*, epileptics, hearing-impaired persons, persons with heart ailments) from participation in programs or activities without regard to an individual's actual ability to participate. Use of an irrebuttable presumption is permissible only when in all cases a physical condition by its very nature would prevent an individual from meeting the essential eligibility requirements for participation in the activity in question. It would be permissible, therefore, to exclude without an individual evaluation all persons who are blind in both eyes from eligibility for a license to operate a commercial vehicle in interstate commerce; but it may not be permissible to automatically disqualify all those who are blind in just one eye.

Section 504, however, prohibits more than just the most obvious denials of equal treatment. It is not enough to admit persons in wheelchairs to a program if the facilities in which the program is conducted are inaccessible. Paragraph (b)(1)(iii), therefore, requires that the opportunity to participate or benefit afforded to a handicapped person be as effective as that afforded to others. The later sections on program accessibility (§§ —.150– —.151) and communications (§ —.160) are specific applications of this principle.

Despite the mandate of paragraph (d) that the agency administer its programs and activities in the most integrated setting appropriate to the needs of qualified handicapped persons, paragraph (b)(1)(iv), in conjunction with paragraph (d), permits the agency to develop separate or different aids, benefits, or services when necessary to provide handicapped persons with an equal opportunity to participate in or benefit from the agency's programs or activities. Paragraph (b)(1)(iv) requires that different or separate aids, benefits, or services be provided only when necessary to ensure that the aids, benefits, or services are as effective as those provided to others. Even when separate or different aids, benefits, or services would be more effective, paragraph (b)(2) provides that a qualified handicapped person still has the right to choose to participate in the program that is not designed to accommodate handicapped persons.

Paragraph (b)(1)(v) prohibits the agency from denying a qualified handicapped person the opportunity to participate as a member of a planning or advisory board.

Paragraph (b)(1)(vi) prohibits the agency from limiting a qualified handicapped person in the enjoyment of any right, privilege, advantage, or opportunity enjoyed by others receiving any aid, benefit, or service.

Paragraph (b)(3) prohibits the agency from utilizing criteria or methods of administration that deny handicapped persons access to the agency's programs or activities. The phrase "criteria or methods of administration" refers to official written agency policies and the actual practices of the agency. This subparagraph prohibits both blatantly exclusionary policies or practices and nonessential policies and practices that are neutral on their face, but deny handicapped persons an effective opportunity to participate.

Paragraph (b)(4) specifically applies the prohibition enunicated in § —.130(b)(3) to the process of selecting sites for construction of new facilities or existing facilities to be used by the agency. Paragraph (b)(4) does not apply to construction of additional buildings at an existing site.

Paragraph (b)(5) prohibits the agency, in the selection of procurement contractors, from using criteria that subject qualified handicapped persons to discrimination on the basis of handicap.

Paragraph (b)(6) prohibits the agency from discriminating against qualified handicapped persons on the basis of handicap in the granting of licenses or certification. A person is a "qualified handicapped person" with respect to licensing or certification, if he or she can meet the essential eligibility requirements for receiving the license or certification (*see* § —.103).

In addition, the agency may not establish requirements for the programs or activities of licensees or certified entities that subject qualified handicapped persons to discrimination on the basis of handicap. For example, the agency must comply with this requirement when establishing safety standards for the operations of licensees. In that case the agency must ensure that standards that it promulgates do not discriminate against the employment of qualified handicapped persons in an impermissible manner.

Paragraph (b)(6) does not extend section 504 directly to the programs or activities of licensees or certified entities themselves. The program or activities of Federal licensees or certified entities are not themselves federally conducted programs or activities nor are they programs or activitities receiving Federal financial assistance merely by virtue of the Federal license or certificate. However, as noted above, section 504 may affect the content of the rules established by the agency for the operation of the program or activity of the licensee or certified entity, and thereby indirectly affect limited aspects of their operations.

Paragraph (c) provides that programs conducted pursuant to Federal statute or Executive order that are designated to benefit only handicapped persons or a given class handicapped persons may be limited to those handicapped persons.

Section—.140 Employment.

Section—.140 prohibits discrimination on the basis of handicap in employment by Executive agencies. This regulation is in accord with a decision of the Fifth Circuit that holds that, despite the resulting overlap of coverage with section 501 of the Rehabilitation Act of 1973 (29 U.S.C. 791), Congress intended section 504 to cover the employment practices of Executive agencies. The court also held that in order to give effect to both section 504 and section 501, the administrative procedures of section 501 must be followed in processing section 504 complaints. *Prewitt* v. *United States Postal Service*, 662, F.2d 292 (5th Cir. 1981). Consistent with that decision, this section provides that the standards, requirements, and procedures of section 501 of the Rehabilitation Act, as established in regulations of the Equal Employment Opportunity Commission (EEOC) at 29 CFR Part 1613, shall be those applicable to employment in federally conducted programs or activities. In addition to this section, § —.170(b) of this regulation specifies that the agency will use the existing EEOC procedures to resolve allegations of employment discrimination. Responsibility for coordinating enforcement of Federal laws prohibiting discrimination in employment is assigned to the EEOC by Executive Order 12067 (43 FR 28967, 3 CFR, 1978 Comp., p. 206). Under this authority, the EEOC establishes government-wide standards on nondiscrimination in employment on the basis of handicap.

Section—.149 Program accessibility: Discrimination prohibited.

Section—.149 states the general nondiscrimination principle underlying the program accessibility requirements of §§ —.150 and—.151.

Section—.150 Program accessibility: Existing facilities.

This regulation adopts the program accessibility concept found in the existing section 504 coordination regulation for programs or activities receiving Federal financial assistance (28 CFR 41.56–.58), with certain modifications. Thus, § —.150 requires that the agency's program or activity, when viewed in its entirety, be readily accessible to and usable by handicapped persons. The regulation also makes clear that the agency is not required to make each of its existing facilities accessible (§ —.150(a)(1)). However, § —.150, unlike 28 CFR 41.56–41.57, places explicit limits on the agency's obligation to ensure program accessibility (§ —.150 (a)(2), (a)(3)).

Paragraph (a)(2), which establishes a special limitation on the obligation to ensure program accessiblity in historic preservation programs, is discussed below in connection with paragraph (b).

Paragraph (a)(3) generally codifies recent case law that defines the scope of the agency's obligation to ensure program accessibility. This subparagraph provides that in meeting the program accessibility requirement the agency is not required to take any action that would result in a fundamental alteration in the nature of its program or activity or in undue financial and administrative burdens. A similar limitation is provided in § —.160(e). This provision is based on the Supreme Court's holding in *Southeastern Community College* v. *Davis*, 442 U.S. 397 (1979), that section 504 does not require program modifications that result in a fundamental alteration in the nature of a program, and on the Court's statement that section 504 does not require modifications that would result in "undue financial and administrative burdens." 442 U.S. at 412. Since *Davis*, circuit courts have applied this limitation on a showing that only one of the two "undue burdens" would be created as a result of the modification sought to be imposed under section 504. *See, e.g., Dopico* v. *Goldschmidt*, 687 F.2d 644 (2d Cir. 1982); *American Public Transit Association* v. *Lewis (APTA)*, 655 F.2d 1272 (D.C. Cir. 1981). Thus, in *APTA* the United States Court of Appeals for the District of Columbia Circuit applied the *Davis* language and invalidated the section 504 regulations of the Department of Transportation (DOT). The court in *APTA* noted "that at some point at transit system's refusal to take modest, affirmative steps to accommodate handicapped persons might well violate section 504. But DOT's rules do not mandate only modest expenditures. The regulations require extensive modifications of existing systems and impose extremely heavy financial burdens on local transit authorities." 655 F.2d at 1278.

The inclusion of paragraph (a)(3) is an effort to conform the agency's regulation implementing section 504 to the Supreme Court's interpretation of the statute in *Davis* as well as to the decisions of lower courts following the *Davis* opinion. This paragraph acknowledges, in light of recent case law, that in some situations, certain accommodations for a handicapped person may so alter an agency's program or activity, or entail such extensive costs and administrative burdens that the refusal to undertake the accommodations is not discriminatory. The failure to include such a provision could lead to judicial invalidation of the regulation or reversal of a particular enforcement action taken pursuant to the regulation.

This paragraph, however, does not establish an absolute defense; it does not relieve the agency of all obligations to handicapped persons. Although the agency is not required to take actions that would result in a fundamental alteration in the nature of a program or activity or in undue financial and administrative burdens, it nevertheless must take any other steps necessary to ensure that handicapped persons receive the benefits and services of the federally conducted program or activity.

It is our view that compliance with § —.150(a) would in most cases not result in undue financial and administrative burdens on the agency. In determining whether financial and administrative burdens are undue, all agency resources available for use in the funding and operation of the conducted program or activity should be considered. The burden of proving that compliance with § —.150(a) would fundamentally alter the nature of a program of activity or would result in undue financial and administrative burdens rests with the agency. The decision that compliance would result in such alteration or burdens must be made by the agency head and must be accompanied by a written statement of the reasons for reaching that conclusion. Any person who believes that he or she or any specific class of persons has been injured by the agency head's decision or failure to make a decision may file a complaint under the compliance procedures established in § —.170.

Paragraph (b)(1) sets forth a number of means by which program accessibility may be achieved, including redesign of equipment, reassignment of services to accessible buildings, and provision of aides. In choosing among methods, the agency shall give priority consideration to those that will be consistent with provision of services in the most integrated setting appropriate to the needs of handicapped persons. Structural changes in existing facilities are required only when there is no other feasible way to make the agency's program accessible. The agency may comply with the program accessibility requirement by delivering services at alternate accessible sites or making home visits as appropriate.

Section —.150(a)(2) provides an additional limitation on the obligation to ensure program accessibility that is applicable only to historic preservation programs. In order to avoid possible conflict between the congressional mandates to preserve historic properties on the one hand and to eliminate discrimination against handicapped persons on the other, § —.150(a)(2) provides that in historic preservation programs the agency is not required to take any action that would result in a substantial impairment of significant historic features of an historic property.

Nevertheless, because the primary benefit of an historic preservation program is uniquely the experience of the historic property itself, § —.150(b)(2) requires the agency to give priority to methods of providing program accessibility that permit handicapped persons to have physical access to the historic property. This priority on physical access may also be viewed as a specific application of the general requirement that the agency administer programs in the most integrated setting appropriate to the needs of qualified handicapped persons (§ —.130(d)). Only when providing physical access would result in a substantial impairment of significant historic features, a fundamental alteration in the nature of the program or in undue financial and administrative burdens, may the agency adopt alternative methods for providing program accessibility that do not ensure physical access. Examples of some alternative methods are provided in § —.150(b)(2).

The special limitation on program accessibility set forth in § —.150(a)(2) is applicable only to programs that have preservation of historic properties as a primary purpose (*see supra* definition of "historic preservation program," § —.103). Narrow application of the special limitation is justified because of the inherent flexibility of the program accessibility requirement. Where historic preservation is not a primary purpose of the program the agency is not bound to a particular facility. It can relocate all or part of its program to an accessible facility, make home visits, or use other standard methods of achieving program accessibility without making structural alterations that might impair significant historic features of the historic property.

Paragraphs (c) and (d) establish time periods for complying with the program accessibility requirement. As currently required for federally assisted programs by 28 CFR 41.57(b), the agency must make any necessary structural changes in facilities as soon as practicable, but in no event later than three years after the effective date of this regulation. Where structural modifications are required, a transition plan shall be developed within six months of the effective date of this regulation. Aside from sturctural changes, all other necessary steps to achieve compliance shall be taken within sixty days. The Department of Jusitce is considering whether and to what degree the Federal Advisory Committee Act (5 U.S.C. app.) is applicable to the proposed consultation requirement included in § —.150(d).

Section—.151 Program accessibility: New construction and alterations.

Overlapping coverage exists with respect to new construction under section 504, section 502 of the Rehabilitation Act of 1973, as amended

(29 U.S.C. 792), and the Architectural Barriers Act of 1968, as amended (42 U.S.C. 4151–4157). Section—.151 provides that those buildings that are constructed or altered by, on behalf of, or for the use of the agency shall be designed, constructed, or altered to be readily accessible to and usable by handicapped persons in accordance with 41 CFR 101–19.600 to 101–19.607. This standard was promulgated pursunt to the Architectural Barriers Act of 1968, as amended (42 U.S.C. 4151–4157). We believe that it is appropriate to adopt the existing Architectural Barriers Act standard for section 504 compliance because new and altered buildings subject to this regulation are also subject to the Architectural Barriers Act and because adoption of the standard will avoid duplicative and possibly inconsistent standards.

Existing buildings leased by the agency after the effective date of this regulation are not required to meet the new construction standard. They are subject, however, to the requirements of § —.150.

Section —.160 Communications.

Section —.160 requires the agency to take appropriate steps to ensure effective communication with personnel of other Federal entities, applicants, participants, and members of the public. These steps shall include procedures for determining when auxiliary aids are necessary under § —.160(a)(1) to afford a handicapped person an equal opportunity to participate in, and enjoy the benefits of, the agency's program or activity. They shall also include an opportunity for handicapped persons to request the auxiliary aids of their choice. This expressed choice shall be given primary consideration by the agency (§ —.160(a)(1)(i)). The agency shall honor the choice unless it can demonstrate that another effective means of communication exists or that use of the means chosen would not be required under § —.160(e). That paragraph limits the obligation of the agency to ensure effective communication in accordance with *Davis* and the circuit court opinions interpreting it (*see supra* preamble § —.150(a)(3)). Unless not required by § —.160(e), the agency shall provide auxiliary aids at no cost to the handicapped person.

It is our view that compliance with § —.160 would in most cases not result in undue financial and administrative burdens on the agency. In determining whether finanicial and administrative burdens are undue, all agency resources available for use in the funding and operation of the conducted program or activity should be considered. The burden of proving that compliance with § —.160 would fundamentally alter the nature of a program or activity or would result in undue financial and administrative burdens rests with the agency. The decision that compliance would result in such alteration or burdens must be made by the agency head and must be accompanied by a written statement of the reasons for reaching that conclusion. Any person who believes that he or she or any specific class of persons has been injured by the agency head's decision or failure to make a decision may file a complaint under the compliance procedures established in § —.170.

In some circumstances, a notepad and written materials may be sufficient to permit effective communication with a hearing-impaired person. In many circumstances, however, they may not be, particularly where the hearing-impaired applicant or participant is not skilled in spoken or written language. Then, a sign language interpreter may be appropriate. For vision-impaired persons, effective communication might be achieved by several means, including readers and audio recordings. In general, the agency intends to make clear to the public (1) the communications services it offers to afford handicapped persons an equal opportunity to participate in or benefit from its programs or activities, (2) the opportunity to request a particular mode of communication, and (3) the agency's preferences regarding auxiliary aids if it can demonstrate that several different modes are effective.

The agency shall ensure effective communication with vision-impaired and hearing-impaired persons involved in hearings conducted by the agency. Auxiliary aids must be afforded where necessary to ensure effective communication at the proceedings. If sign language interpreters are necessary, the agency may require that it be given reasonable notice prior to the proceeding of the need for an interpreter. Moreover, the agency need not provide individually prescribed devices, readers for personal use or study, or other devices of a personal nature (§ —.160(a)(1)(ii)). For example, the agency need not provide eye glasses or hearing aids to applicants or participants in its programs. Similarly, the regulation does not require the agency to provide wheelchairs to persons with mobility impairments.

Paragraph (b) requires the agency to provide information to handicapped persons concerning accessible services, activities, and facilities. Paragraph (c) requires the agency to provide signage at inaccessible facilities that directs users to locations with information about accessible facilities.

Paragraph (d) requires the agency to take appropriate steps to ensure that information regarding section 504 rights and protections that is supplied to employees, applicants, participants, beneficiaries, and other interested persons under § —.111 is effectively communicated to handicapped persons.

Section —.170 Compliance procedures.

Paragraph (a) specifies that paragraphs (c) through (l) of this section establish the procedures for processing complaints other than employment complaints. Paragraph (b) provides that the agency will process employment complaints according to procedures established in existing regulations of the EEOC (29 CFR Part 1613) pursuant to section 501 of the Rehabilitation Act of 1973 (29 U.S.C. 791).

The agency will designate an official responsible for coordinating implementation of this section § —.170(c).

The agency is required to accept and investigate all complete complaints (§ —.170(d)). If it determines that it does not have jurisdiction over a complaint, it shall promptly notify the complainant and make reasonable efforts to refer the complaint to the appropriate entity of the Federal government (§ —.170(e)).

Paragraph (f) requires the agency to notify the Architectural and Transportation Barriers Compliance Board upon receipt of a complaint alleging that a building or facility subject to the Architectural Barriers Act or section 502 was designed, constructed, or altered in a manner that does not provide ready access and use to handicapped persons.

Paragraph (g) requires the agency to provide to the complainant, in writing, findings of fact and conclusions of law, the relief granted if noncompliance is found, and notice of the right to appeal (§ —.170(g)). One appeal within the agency shall be provided (§ —.170(i)). The appeal will not be heard by the same person who made the initial determination of compliance or noncompliance (§ —.170(i)).

Paragraph (l) permits the agency to delegate its authority for investigating complaints to other Federal agencies. However, the statutory obligation of the agency to make a final determination of compliance or noncompliance may not be delegated.

ADDRESSES: Comments should be sent to: Secretary, U.S. Nuclear Regulatory Commission, 1717 H Street NW, Washington, DC 20555, Attention: Docketing and Service Branch.

Comments received will be available for public inspection at NRC Public Document Room, 1717 H Street NW, Washington, DC 20555 from 8:15 A.M. to 5:00 P.M. Monday through Friday except legal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Edward E. Tucker, Office of Small and Disadvantaged Business Utilization/Civil Rights, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: (301) 492-7697, TDD: (202) 724-7678.

List of Subjects in 10 CFR Part 4

Administrative practice and procedure, Blind, Civil Rights, Disabled, Discrimination against handicapped, Equal employment opportunity, Federal building and facilities, Handicapped, Nondiscrimination, Physically handicapped.

It is proposed that Title 10 of the Code of Federal Regulations be amended by adding Subpart E to Part 4 as set forth at the end of this document.

William J. Dircks,
Executive Director for Operations.

PART 4—[AMENDED]

Part 4, Subpart E—*Enforcement of Nondiscrimination on the Basis of Handicap in Programs or Activities Conducted by U.S. Nuclear Regulatory Commission*

Sec.
4.501 (—.101) Purpose.
4.502 (—.102) Application.
4.503 (—.103) Definitions.
4.504 (—.104) to 4.509 (—.109) [Reserved]
4.510 (—.110) Self-evaluation.
4.511 (—.111) Notice.
4.512 (—.112) to 4.529 (—.129) [Reserved]
4.530 (—.130) General prohibitions against discrimination.
4.531 (—.131) to 4.539 (—.139) [Reserved]
4.540 (—.140) Employment.
4.541 (—.141) to 4.548 (—.148) [Reserved]
4.549 (—.149) Program accessibility: Discrimination prohibited.
4.550 (—.150) Program accessibility: Existing facilities.
4.551 (—.151) Program accessibility: New construction and alterations.
4.552 (—.152) to 4.559 (—.159) [Reserved]
4.560 (—.160) Communications.
4.561 (—.161) to 4.569 (—.169) [Reserved]
4.570 (—.170) Compliance procedures.
4.571 (—.171) to 4.999 (—.999) [Reserved]

Authority: 29 U.S.C. 794.

PART 4

NONDISCRIMINATION IN FEDERALLY ASSISTED COMMISSION PROGRAMS

STATEMENTS OF CONSIDERATION

29 FR 19277
Published 12/31/64
Effective 1/30/65

Effectuation of Title VI of the Civil Rights Act of 1964

The Atomic Energy Commission hereby amends its regulations by adding the following new Part 4, "Nondiscrimination in Federally Assisted Commission Programs".

Pursuant to the Civil Rights Act of 1964 and the Administrative Procedure Act of 1946, the following new Part 4 of Title 10, Chapter I, Code of Federal Regulations, is published as a document subject to codification to be effective on the thirtieth day following its publication in the FEDERAL REGISTER.

38 FR 2330
Published 1/24/73
Effective 1/24/73

Miscellaneous Amendment

See Part 2 Statements of Consideration.

38 FR 17927
Published 7/5/73
Effective 7/5/73

Miscellaneous Amendments

40 FR 8774
Published 3/3/75
Effective 3/3/75

Energy Reorganization Act; Revision to Chapter 1 to Reflect Organizational and Procedural Changes

See Part 2 Statements of Consideration.

45 FR 18905
Published 3/24/80
Effective 3/24/80

10 CFR Parts 4, 20, 30, 40, 50, 55, 70, 110, and 150

Deletion of reference to Panama Canal Zone; Minor Amendments

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is deleting all references to the Panama Canal Zone in its regulations. These minor amendments reflect the provisions of the Panama Canal Treaty of 1977 and the recently enacted Panama Canal Defense Act of 1979. Under the Act and the Treaty, the U.S. Government relinquished jurisdiction over the Panama Canal Zone to the Republic of Panama. These amendments revise portions of the Commission's regulations to reflect the revised status of the Canal Zone.

EFFECTIVE DATE: March 24, 1980.

FOR FURTHER INFORMATION CONTACT: Joseph M. Felton, Director, Divison of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: 301–492–7211.

SUPPLEMENTARY INFORMATION: Under the Panama Canal Treaty of 1977, the territory of the former Panama Canal Zone became subject to the jurisdiction of the Republic of Panama on October 1, 1979. The Treaty, and the recently enacted Panama Canal Defense Act of 1979 (P.L. 96–70) passed on September 27, 1979, supersede all previous legislation. Thus, all references in the Atomic Energy Act to the Canal Zone as being jurisdictionally part of the United States are no longer valid. Therefore, the Nuclear Regulatory Commission is deleting all references to the Canal Zone from its regulations in Title 10, Chapter 1 of the Code of Federal Regulations.

Since these amendments are corrective and relate solely to minor procedural matters, notice of proposed rulemaking and public procedure thereon are unnecessary and good cause exists to make the amendments effective upon publication in the **Federal Register.**

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter 1, Code of Federal Regulations, Parts 4, 20, 30, 40, 50, 55, 70, 110 and 150 are published as a document subject to codification.

45 FR 14533
Published 3/6/80
Effective 5/20/80

10 CFR Part 4

Nondiscrimination in Federally Assisted Commission Programs; Application to the Handicapped

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations to implement the requirements of section 504 of the Rehabilitation Act of 1973, as amended. The amendment makes it unlawful for any recipient of Federal financial assistance to discriminate against a qualified handicapped person, on the basis of handicap, in employment or the receipt of services.

EFFECTIVE DATE: The amendment becomes effective on May 20, 1980.

FOR FURTHER INFORMATION CONTACT: Jay W. Maynard, Office of the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (phone: 301–492–8668).

SUPPLEMENTARY INFORMATION: On May 8, 1979, the NRC published for a 60-day comment period a proposed rule (44 FR 26887) to amend its regulations in 10 CFR Part 4. The proposed rule implements section 504 of the Rehabilitation Act of 1973, as amended, by prohibiting discrimination in federally assisted Commission programs on the basis of a physical or mental handicap.

In Executive Order 11914, "Nondiscrimination with Respect to the Handicapped in Federally Assisted Programs," dated April 28, 1976, the President directed that all Federal agencies empowered to provide Federal financial assistance issue rules, regulations, and directives consistent with standards and procedures established by the Secretary of Health, Education, and Welfare (HEW). The rule is consistent with that directive and the HEW Guidelines published in the **Federal Register**, January 13, 1978 (43 FR 2131), codified at 45 CFR Part 85.

The amendments restructure 10 CFR Part 4 into two subparts. Except for minor changes, Subpart A reflects those regulations previously promulgated by the Commission to implement Title VI of the Civil Rights Act of 1964 and Title IV of the Energy Reorganization Act of 1974, which relate to nondiscrimination with respect to sex, race, color, or national origin in any program or activity receiving financial assistance from the NRC. The new Subpart B implements section 504 of the Rehabilitation Act of 1973, as amended, and is devoted exclusively to prohibiting discrimination against qualified handicapped persons in employment and in the operation of programs and activities receiving financial assistance from the NRC.

The NRC currently provides financial assistance in the form of training programs for state personnel. The training is performed pursuant to section 274 of the Atomic Energy Act of 1954, as amended, which provides for state assumption of certain areas of NRC regulatory activity. This "Agreement States Program" is designed to improve the state employees' technical and administrative skills as well as develop an understanding and ability to apply regulatory concepts and procedures. NRC also provides financial assistance through programs designed to train state and local government personnel in developing or improving their radiological emergency response plans. More recent authorization for NRC involvement in financial assistance derives from the Uranium Mill Tailings Radiation Control Act of 1978, Pub. L. 95–604, 92 Stat. 3021. Section 207 of the Act authorizes the NRC to provide grants in Fiscal Year 1980 to eligible Agreement States to aid in the development of state regulatory programs which implement certain provisions of the Act.

Thirteen comment letters were received from state and Federal agencies, educational institutions, and public interest groups. Eight comment letters, primarily from state recipients of NRC financial assistance, contained no objections to the adoption of the rule as proposed. The remaining commenters made a number of suggestions which have been adopted in the final rule. Following is a summary of the principal substantive revisions to the regulations.

The term "responsible NRC official" is used in Subparts A and B of Part 4. To more accurately reflect the present responsibilities within NRC for assuring compliance with Part 4, § 4.3(i) of the General Provisions has been revised to define "responsible NRC official" as the Director for Equal Employment Opportunity or any other NRC official to whom the Executive Director for Operations has delegated the authority to act under Part 4 of the Commission's regulations.

The requirement found in § 4.123 that recipients make "reasonable accommodation" to the limitations of the handicapped unless the recipient can demonstrate "undue hardship" has been clarified. Subsections (b) and (c) have been added which set forth examples of "reasonable accommodation" and factors to be considered in determining whether an accommodation would impose an "undue hardship" on the operations of a recipient's program. Subsection (d) also has been added to state explicitly that employment may not be denied to a qualified handicapped employee or applicant if the basis for denial is the need to make reasonable accommodation.

Section 4.124, "Employment Criteria," also has been clarified. Subsection (a) now states that job-related employment tests or criteria which screen out handicapped persons may not be used unless alternative job-related tests or criteria that do not have that effect are not available. Subsection(b) requires recipients to ensure that employment tests administered to handicapped applicants or employees accurately reflect aptitude or other factors the tests purport to measure, rather than reflect the applicant's or employee's handicap (except where those imparied skills are the factors that the tests seek to measure).

Subsection (b) of § 4.128 is a new provision. It states that the American National Standards Institute specification ANSI A117.1–1961 (R1971) may be utilized in complying with the requirement in subsection (a) that new facilities and, to the maximum extent feasible, alterations to existing facilities be constructed so that they are readily accessible to and usable by handicapped persons. Federal financial assistance which the NRC currently provides does not include assistance for construction or alteration of facilities by recipients. Should NRC fund such assistance in the future, recipients will be required to comply with the provisions of Section 504 as well as the Architectural Barriers Act (42 U.S.C. 4151 et seq.), as implemented by the Architectural and Transportation Barriers Compliance Board.

Section 4.231 has been divided into six subsections. Subsections (a) and (b) clarify that the assurance of compliance submitted by a recipient will obligate the recipient for the period during which financial assistance is extended and allow the assurance to be incorporated by reference in a subsequent application for assistance. Subparagraph (c) makes clear a recipient's responsibility to take remedial action when the responsible NRC official finds a violation of section 504 or Subpart B of Part 4 of the Commission's regulations. Where another recipient exercises control over the recipient that has discriminated, the responsible official may require either or both recipients to take remedial action. Remedial action may be required with respect to former participants in the recipient's program or persons who would have been participants had the discrimination not occurred. Subsection (d) clarifies that a recipient may voluntarily undertake action to overcome effects of limited participation of handicapped persons in the recipient's program without a formal finding of discrimination by the responsible NRC official. Subsection (e) adds the requirement that the records of self-evaluations conducted by recipients shall be maintained for public and NRC inspection for a period of three years and specifies the contents of those records. Subsection (f) requires each recipient to designate at least one person to coordinate its efforts to comply with Subpart B of Part 4.

The notice requirement of § 4.231 of the proposed rule has been expanded and relocated in § 4.232. Those who must be notified that the recipient does not discriminate on the basis of handicap now include participants in federally assisted programs, applicants, and unions or professional organizations holding collective bargaining or professional agreements with recipients. The section also sets forth approved methods for providing notice; certain provisions which must be included in the notice; and guidance with respect to certain materials published by recipients of Federal assistance.

Several comments were made which did not result in changes to the final rule. One commenter urged that the self-study requirements in the proposed regulations be met by prior self-studies completed for other Federal agencies. The NRC will accept prior self-studies completed for other Federal agencies to the extent they encompass the programs and activities which receive NRC financial assistance and otherwise satisfy NRC requirements. It was not believed necessary to change the rule to incorporate the comment because the rule does not prohibit the use of such self-evaluations.

Another commenter recommended that the proposed 504 regulations not be finalized until they "reflect the requirements of the 1978 amendments" to the Rehabilitation Act, which according to the commenter, applies section 504 to employment discrimination only where the primary objective of Federal financial assistance is to provide employment. The commenter cited as authority for its objection the ruling of the Fourth Circuit Court of Appeals in "Trageser v. Libbie Rehabilitation Center, Inc." 590 F. 2d 87 (4th Cir. 1978), cert. denied —— U.S. ——, 99 S.Ct. 2985 (1979).

Congress amended section 504 in 1978 to state that the "remedies, procedures, and rights set forth in Title VI of the Civil Rights Act of 1964 shall be available to any person aggrieved (under section 504)." The court in "Trageser" observed that the 1978 amendments made section 504 coextensive with Title VI of the Civil Rights Act. The court held that since Title VI limits relief in the area of employment discrimination to circumstances where a primary objective of the Federal assistance is to provide employment, relief under the coextensive section 504 must be similarly limited.

This comment and similar comments made to other Federal agencies have been considered by the former Department of Health, Education, and Welfare (HEW) (now the Department of Health and Human Services). HEW has advised in a recently written opinion that it considers the "Trageser" decision "poorly reasoned and should not be followed outside the Fourth Circuit . . . ." HEW argues that the legislative history of the 1978 amendments to section 504 clearly demonstrates that Congress intended to establish only procedural rights of persons aggrieved by violations of section 504. It does not believe that this amendment to the Act demonstrates Congressional intent to curtail the substantive rights of handicapped persons under section 504. In light of the lead role granted to that agency by Executive Order 11914, the NRC has decided not to change its regulations in this area from those which were originally proposed.

Changes to the proposed regulations are summarized as follows:

1. The definition of "Responsible NRC official" in § 4.3 has been amended.
2. Subsections (b), (c), and (d) have been added to § 4.123.
3. Section 4.124 has been revised and divided into two paragraphs.
4. The language of subsections 4.125(b) and 4.127 (b) and (d) has been clarified.
5. A new paragraph (b) has been added to § 4.128.
6. Section 4.231 has been expanded and divided into six subsections.
7. The notice provision formerly found in § 4.231 has been revised and renumbered as § 4.232.
8. Section 4.232 in the proposed rule regarding enforcement procedures has been renumbered and appears as § 4.233 in the final rule.
9. Appendix A has been revised to reflect NRC financial assistance which is granted under the authority of the Uranium Mill Tailings Radiation Control Act of 1978.

The final rule has been reviewed by the Office of Civil Rights, HEW; Office of Interagency Coordination, Equal Employment Opportunity Commission; and the Architectural and Transportation Barriers Compliance Board.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 522 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter 1, Code of Federal Regulations, Part 4, are published as a document subject to codification.

≫49 FR 19623
Published 5/9/84
Effective 5/9/84

Information Collection Requirements; Display of OMB Control Numbers

See Part 0 Statements of Consideration

PART 7

ADVISORY COMMITTEES

Sec.
7.1 Purpose and applicability.
7.2 Definitions.
7.3 Policy.
7.4 Interpretations.
7.5 Advisory committee management officer.
7.6 Establishment of advisory committees.
7.7 Charter.
7.8 Meetings.
7.9 Closed meetings.
7.10 Designated federal officer or employee.
7.11 Public notice.
7.12 Minutes.
7.13 Transcripts of advisory committee meetings.
7.14 Annual comprehensive review.
7.15 Termination and renewal of advisory committees.
7.16 Reports about advisory committees.
7.17 Availability of documents and information on advisory committees.
7.18 Uniform pay guidelines.
7.19 Fiscal and administrative responsibilities.

AUTHORITY: Sec. 161, Pub. L. 83–703, 68 Stat. 948, (42 USC 2201); sec. 201(f), Pub. L. 93–438, 88 Stat. 1243; Pub. L. 92–463, 86 Stat. 770 (5 USC Appendix I).

§ 7.1 Purpose and applicability.

(a) The regulations in this part implement the Federal Advisory Committee Act (86 Stat. 770), Executive Order No. 11769 (39 FR 7125) and Office of Management and Budget Circular No. A–63. The provisions of the Federal Advisory Committee Act and this part shall apply to each advisory committee established by the Commission, including advisory committees created pursuant to sections 29 and 161a of the Atomic Energy Act of 1954, as amended, except to the extent that any Act of Congress establishing an advisory committee reporting to the Commission specifically provides otherwise.

(b) This part does not apply to interagency advisory committees or advisory committees established by the President unless specifically made applicable by the establishing authority.

(c) This part does not apply to any local civic group whose primary function is that of rendering a public service with respect to a Federal program, or any State or local committee, council, board, commisison, or similar group established to advise or make recommendations to State or local officials or agencies.

40 FR 8774

§ 7.2 Definitions.

As used in this part:

(a) "Act" means the Federal Advisory Committee Act (86 Stat. 770).

(b) "Advisory Committee" has the meaning set forth in section 3(2) of the Act.

(c) "Commission" means the Nuclear Regulatory Commission of five members, or a quorum thereof, sitting as a body, as provided by section 201(a) of the Energy Reorganization Act of 1974 (88 Stat. 1242).

(d) "Director" means the Director of the Office of Management and Budget.

(e) "NRC" means the Nuclear Regulatory Commission.

(f) "OMB" means the Office of Management and Budget.

(g) "Presidential advisory committee" means an advisory committee which advises the President.

(h) "Secretariat" means the Committee Management Secretariat of the Office of Management and Budget.

40 FR 8774

§ 7.3 Policy.

In determining whether an advisory committee should be created and in reviewing the functions of operating advisory committees, the Commission will:

(a) Establish new advisory committees only when they are determined to be essential, keeping their number to the minimum necessary;

(b) Provide standards and uniform procedures to govern the establishment, operation, administration, and duration of advisory committees;

(c) Terminate advisory committees when they are no longer carrying out the purposes for which they were established;

(d) Keep the Congress and the public informed with respect to the number, purpose, membership, activities, and cost of advisory committees; and

(e) Insure that the function of advisory committees should be advisory only, and that all matters under their consideration should be determined, in accordance with law, by the official or officer involved.

§ 7.4 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by an officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

§ 7.5 Advisory committee management officer.

(a) The Commission will designate an Advisory Committee Management Officer who shall:

(1) Exercise control and supervision over the establishment, procedures, and accomplishments of advisory committees established by the Commission;

(2) Assemble and maintain the reports, records, and other papers of any advisory committee during its existence; and

(3) Carry out, on behalf of the Commission, the provisions of 5 U.S.C. 552 with respect to the reports, records, and other papers designated in paragraph (a)(2) of this section.

(b) The name of the Advisory Committee Management Officer designated in accordance with this part shall be provided to the Secretariat.

40 FR 8774

§ 7.6 Establishment of advisory committees.

(a) No advisory committee shall be established under this part unless such establishment is:

(1) Specifically authorized by statute or by the President; or

(2) Determined as a matter of formal record by the Commission after consultation with the Secretariat, with timely notice published in the FEDERAL REGISTER, to be in the public interest in connection with the performance of duties imposed on the Commission by law.

(b) The determination required by paragraph (a) of this section shall:

(1) Contain a clearly defined purpose for the advisory committee;

(2) Require the membership of the advisory committee to be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee;

(3) Contain appropriate provisions to assure that the advice and recommendations of the advisory committee will not be inappropriately influenced by the appointing authority or by any special interest, but will instead be the result of the

advisory committee's independent judgment;

(4) Contain provisions dealing with the date for submission of reports (if any), the duration of the advisory committee, and the publication of reports and other materials, to the extent that the Commission determines the provisions of § 7.16 to be inadequate; and

(5) Contain provisions which will assure that the advisory committee will have adequate staff (either supplied by the Commission or employed by it), will be provided adequate quarters, and will have funds available to meet its other necessary expenses.

(c) Consultation with the Secretariat may be in the form of a letter from the Commission describing the nature and purpose of the proposed advisory committee, including an explanation of why the functions of the proposed committee could not be performed by the NRC or by an existing committee. The letter should describe the Commission's plan to attain balanced membership on the proposed committee as prescribed in paragraph (b) of this section. If the Secretariat is satisfied that establishment of the advisory committee would be in accord with the Act, the Commission shall certify in writing that creation of the advisory committee is in the public interest.

(d) Unless otherwise specifically provided by statute or Presidential directive, advisory committees shall be utilized solely for advisory functions.

40 FR 8774

§ 7.7 Charter.

(a) No advisory committee established under this part shall meet or take any action until an advisory committee charter has been filed with the Commission and the Joint Committee on Atomic Energy.

(b) The charter required by paragraph (a) of this section shall contain the following information:

(1) The committee's official designation;

(2) The committee's objectives and the scope of its activity;

(3) The period of time necessary for the committee to carry out its purposes;

(4) The agency or official to whom the committee reports;

(5) The agency responsible for providing the necessary support for the committee;

(6) A description of the duties for which the committee is responsible, and, if such duties are not solely advisory, a specification of the authority for such functions;

(7) The estimated annual operating costs in dollars and man years for such committee;

(8) The estimated number and frequency of committee meetings;

(9) The committee's termination date, if less than two years from the date of the committee's establishment; and

(10) The date the charter is filed.

(c) A copy of the charter required by paragraph (a) of this section shall also be furnished at the time of filing to the Library of Congress, Exchange and Gift Division, Federal Advisory Committee Desk, Washington, D.C. 20540.

(d) An amendment to the charter may be filed if a substantial change occurs with regard to matters stated in the charter originally filed.

(e) The requirements of this section apply to committees utilized as advisory committees, though not established for that purpose.

40 FR 8774

§ 7.8 Meetings.

(a) Advisory committees established under this part shall not hold any meetings except at the call of, or with the advance approval of, the federal officer or employee designated in accordance with § 7.10, with an agenda approved by such officer or employee. Timely notice of each meeting shall be provided in accordance with § 7.11.

(b) The agenda required by paragraph (a) of this section shall list the matters to be considered at the meeting.

42 FR 12875

It shall also indicate when any part of the meeting will concern matters within the exceptions of the Government in the Sunshine Act, 5 U.S.C. 552b and § 9.104 of this chapter.

40 FR 8774

(c) Subject to the provisions of § 7.9, each advisory committee meeting shall be open to the public. Meetings open in whole or in part to the public shall be held at a reasonable time and at a place that is reasonably accessible to the public. The size of the meeting room shall be determined by such factors as the size of the committee, the number of members of the public who could reasonably be expected to attend, the number of persons who attended similar meetings in the past, and the resources and facilities available.

(d) Any member of the public shall be permitted to file a written statement with the committee related to any meeting that is open in whole or in part to the public. Interested persons may also be permitted by the committee chairman to speak at such meetings in accordance with procedures established by the committee.

42 FR 12875

§ 7.9 Closed meetings.

(a) The requirements of § 7.8 (c) and (d) that meetings shall be open to the public and that the public shall be afforded an opportunity to participate shall not apply to any advisory committee meeting which the President or the Commission determines is concerned with matters listed in 5 U.S.C. 552b(c) and Sec. 9.104 of this chapter.

40 FR 8774

(b) An advisory committee which seeks to have all or part of a meeting closed shall notify the Commission before the scheduled date of the meeting. The notification shall be in writing and shall specify the reasons why any part of the meeting should be closed.

(c) A request that a meeting be closed will be granted upon a determination by the Commission that the request is in accordance with the policies of this part. The Commission's determination will be in writing and will state the specific reasons for closing all or part of the meeting. The determination will be made available to the public on request.

(d) The Commission may delegate responsibility for making the determination required by paragraph (c) of this section. In any case where a determination to close a meeting is made by the Commission's delegate, the determination shall be reviewed by the General Counsel.

42 FR 12875

(e) When a meeting is closed to the public, the advisory committee shall issue a report at least annually setting forth a summary of its activities and such related matters as would be informative to the public consistent with the policy of 5 U.S.C. 552b(c) and Subpart C of Part 9 of this chapter. Notice of availability of such annual report shall be published in accordance with § 7.11.

40 FR 8774

§ 7.10 Designated federal officer or employee.

(a) The Commission will designate an officer or employee of the Federal Government to chair or attend each meeting of each advisory committee established under this part.

(b) No advisory committee shall conduct any meeting in the absence of the Federal employee or officer designated in accordance with paragraph (a) of this section.

(c) The Federal officer or employee designated in accordance with paragraph (a) of this section is authorized, whenever he determines it to be in the public interest, to adjourn any committee meeting he is designated to chair or attend.

§ 7.11 Public notice.

(a) The Commission's certification prescribed by § 7.6 that creation of the advisory committee is in the public interest and a description of the nature and purpose of the committee shall be published in the FEDERAL REGISTER at least 15 days prior to the filing of the committee's charter, unless the Secretariat, for good cause, authorizes a shorter period of time between publication of the notice and the filing of the charter.

(b) Except when the Director determines otherwise for reasons of national security, timely notice of each advisory committee meeting, whether open or closed to the public, shall be published in the FEDERAL REGISTER at least 15 days before the meeting date. Such notice should state the name of the advisory committee, the time, place and purpose of the meeting, and should include, where appropriate, a summary of the meeting agenda. Notices ordinarily should state that meetings are open to the public or explain why the meeting or any portion of a meeting is to be closed. Notice shorter than the time prescribed by this paragraph may be provided in emergency situations, and the reason for such emergency exceptions shall be made part of the meeting notice. A request for a determination that notice of a meeting should not be published for reasons of national security shall be submitted to the Director with a statement of reasons supporting the request at least 30 days before the meeting is scheduled.

(c) In addition to the notice required by paragraph (b) of this section, other forms of notice such as public releases and notice by mail should be used to inform the public of advisory committee meetings.

(d) The Secretary of the Commission should, where practicable, maintain lists of people and organizations interested in particular advisory committees and notify them of meetings by mail.

(e) Notice of the availability of the annual report required by § 7.9(e) will be published in the FEDERAL REGISTER no later than 60 days after its completion. The notice will include instructions which will allow the public access to the report.

40 FR 8774

§ 7.12 Minutes.

(a) Detailed minutes of each meeting of each advisory committee shall be kept and shall contain a record of the persons present, a complete summary of matters discussed and conclusions reached, and copies of all reports received, issued, or approved by the advisory committee. The record of persons present shall include the time and place of the meeting, a list of advisory committee members and staff and agency employees present at the meeting, a list of members of the public who presented oral or written statements, and an estimate of the number of members of the public who attended the meeting. The minutes shall describe the extent to which the meeting was open to the public and the extent of public participation. If it is impracticable to attach a report received, issued or approved by the advisory committee to the minutes, the minutes will describe the report in sufficient detail to enable any person requesting the report to readily identify it.

(b) The accuracy of all minutes shall be certified to by the chairman of the advisory committee concerned, except that in the case of a subcommittee or subgroup of the advisory committee, the accuracy of minutes shall be certified to by the chairman of the subcommittee or subgroup concerned.

§ 7.13 Transcripts of advisory committee meetings and agency proceedings.

Except where prohibited by contractual agreements entered into prior to January 5, 1973, copies of transcripts which have been prepared of advisory committee meetings will be made available to any person at the actual cost of duplication prescribed in Part 9 of this chapter.

41 FR 55851

§ 7.14 Annual comprehensive review.

(a) The Commission will conduct an annual comprehensive review of the activities and responsibilities of each advisory committee to determine:

(1) Whether such committee is carrying out its purpose;

(2) Whether, consistent with the provisions of applicable statutes, the responsibilities assigned to it should be revised;

(3) Whether it should be merged with other advisory committees; or

(4) Whether it should be abolished.

(b) Pertinent factors to be considered in the comprehensive review required by paragraph (a) of this section include the following:

(1) The number of times the committee has met in the past year;

(2) The number of reports or recommendations submitted by the committee;

(3) An evaluation of the substance of the committee's reports or recommendations with regard to the Commission's programs or operations;

(4) An evaluation (placing emphasis on the most recent 12 month period of the committee's work) of the history of Commission utilization of the committee's recommendations in policy formulation; program planning; decision making; accomplishing program objectives more effectively; and achieving economics in programs;

(5) Whether the information or recommendations could be obtained from sources within the Commission or from another advisory committee already in existence;

(6) The degree of duplication of effort by the committee as compared to other parts of the agency or other advisory committees; and

(7) The estimated annual cost of the committee.

(c) The annual review required by this section shall be conducted on a calendar-year basis, and the results of the review will be included in the annual report to the Secretariat required by § 7.16(b). The report shall contain a justification for each advisory committee which the Commission determines should be continued, making reference, as appropriate, to the factors specified in paragraph (b) of this section.

(d) The review will examine all advisory committees, and committees found to be no longer needed will be terminated. Advisory committees established by an Act of Congress or the President will be reviewed, and if appropriate, their termination recommended.

40 FR 8774

§ 7.15 Termination and renewal of advisory committees.

(a) Each advisory committee shall terminate not later than the expiration of the two-year period beginning on the date of its establishment unless:

(1) In the case of an advisory committee established by the President or an officer of the Federal Government such advisory committee is renewed by the President or such officer by appropriate action prior to the end of such period; or

(2) In the case of an advisory committee established by an Act of Congress, its duration is otherwise provided for by law.

(b) Any advisory committee which is renewed by the President or any officer of the Federal Government may be continued only for successive two-year periods by appropriate action taken by the President or such officer prior to the date on which such advisory committee would otherwise terminate.

(c) Before it renews a non-statutory advisory committee in accordance with paragraphs (a) or (b) of this section, the Commission will inform the Secretariat by letter not more than 60 days nor less than 30 days before the committee expires of the following: (1) its determination that renewal is necessary and is in the public interest; (2) the reasons for its determination; (3) the Commission's plan to attain balanced membership of the committee; and (4) an explanation of why the committee's functions cannot be performed by the NRC or by an existing advisory committee. After concurrence by the Secretariat, the Commission will certify in writing that the renewal of the advisory committee is in the public interest and will publish a notice of the renewal in the FEDERAL REGISTER and will file a new charter in accordance with § 7.7 of this part.

40 FR 8774

(d) Any advisory committee established by an Act of Congress shall file a charter in accordance with § 7.7 upon the expiration of each successive two-year period following the date of enactment of the Act establishing such advisory committee. The Advisory Committee on Reactor Safeguards shall file a charter in accordance with § 7.7 upon the expiration of each successive two-year period after January 5, 1975.

(e) No advisory committee required under this section to file a charter shall take any action, other than preparation and filing of such charter, between the date the new charter is required and the date on which such charter is filed.

(f) For purposes of this section:

(1) "Any officer of the Federal Government" shall mean the Commission with respect to advisory committees established by the Commission;

(2) "Nonstatutory advisory committee" shall mean an advisory committee not established by statute or reorganization plan.

§ 7.16 Reports about advisory committees.

(a) The Commission will furnish a report on the activities of NRC advisory committees annually to the Administrator, General Services Administration, in accordance with Federal Property Management Regulations Temporary Regulation B–1.

(b) The Commission will furnish a report on the activities of NRC advisory committees annually to the Secretariat in accordance with OMB Circular A–63.

(c) The Commission will inform the Secretariat by letter of the termination or other significant changes with respect to its advisory committees no later than 10 working days following the end of the month in which the change occurred. If no changes are made during any given month, a report to the Secretariat is not required.

§ 7.17 Availability of documents and information on advisory committees.

(a) Subject to the provisions of Parts 2 and 9 of this chapter, the records, reports, transcripts, minutes, appendixes, working papers, drafts, studies, agenda, or other documents which were made available to or prepared for or by each advisory committee shall be available for public inspection and copying at a single location in the NRC Public Document Room, 1717 H Street, NW., Washington, D.C.

(b) The Commission will maintain systematic information on the nature, functions, and operations of each of its advisory committees. A complete set of the charters of the Commission's advisory committees and copies of the annual reports required by § 7.16 will be maintained for public inspection in the NRC Public Document Room.

40 FR 8774

§ 7.18 Uniform pay guidelines.

(a) *Members*. Subject to the provisions of this section, the pay of the member of an advisory committee shall be fixed at the daily equivalent of a rate of the Commission's General Salary Schedule unless the members are appointed as consultants and compensated as provided in paragraph (c) of this section. In determining an appropriate rate of pay for the members of an advisory committee, consideration shall be given to the significance, scope, and technical complexity of the matters with which the advisory committee is concerned and the qualifications required of the members of the advisory committee. The pay of the members of an advisory committee shall not be fixed at a rate higher than the daily equivalent of the maximum rate for GG–15 unless the Commission has determined that, under the factors set forth in this paragraph, a higher rate of pay is justified and necessary. Such a determination will be reviewed annually by the Commission.

(b) *Advisory committee staff*. The pay of each member of the staff of an advisory committee shall be fixed at a rate of the General Salary Schedule in which the staff member's position would be appropriately placed in the NRC Evaluation System applicable to the position. The pay of a member of the staff of an advisory committee shall not be fixed at a rate higher than the daily equivalent of the maximum rate for GG–15 unless the Commission has determined that, under its Evaluation System, the staff member's position would appropriately be placed in the General Salary Schedule grade higher than GG–15. Such a determination will be reviewed by the Commission annually.

(c) *Consultants*. The rate of pay of a consultant to an advisory committee shall not exceed the maximum rate of pay which the Commission may pay experts and consultants under 5 U.S.C. 3109. Consideration shall be given to the qualifications required of the consultant and the significance, scope, and technical complexity of the work in fixing the rate of pay for the consultant.

(d) *Voluntary services*. The provisions of this section shall not prevent the Commission from accepting the voluntary services of a member of an advisory committee, or a member of the staff of an advisory committee, provided that the Commission has authority to accept such services without compensation.

(e) *Reimbursable travel expenses*. The members of an advisory committee, and the staff thereof, while engaged in the performance of their duties away from their homes or regular places of business, may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by 5 U.S.C. 5703 for persons employed intermittently in the government service.

40 FR 8774

§ 7.19 Fiscal and administrative responsibilities.

(a) The Controller shall keep records as will fully disclose the disposition of any funds which may be at the disposal of NRC advisory committees.

(b) The Office of Administration shall keep records as will fully disclose the nature and extent of activities of NRC advisory committees.

(c) Support services shall be provided by NRC for each advisory committee established by or reporting to it unless the establishing authority provides otherwise. Where any such advisory committee reports to more than one agency, only one agency shall be responsible for support services at any one time, and the establishing authority shall designate the agency responsible for providing such services.

ADVISORY COMMITTEES

PETITIONS FOR RULE MAKING

≫49 FR 43070
Published 10/26/84
Comment period expires 12/26/84.

10 CFR Part 7

[Docket No. PRM-7-2]

John L. Nantz; Filing of Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of receipt of petition for rulemaking from John L. Nantz.

SUMMARY: The Commission is publishing for public comment this notice of receipt of a petition for rulemaking which was filed with the Commission by John L. Nantz. The petition was docketed by the Commission on July 25, 1984, and has been assigned Docket No. PRM-7-2. The petitioner requests that the Commission amend its regulations to establish a formal procedure to allow interested persons to petition the Commission to reconsider the decisions of the Commission or its delegates regarding closure of advisory committee meetings or portions of those meetings.

DATE: Comment period expires December 26, 1984. Comments received after this date will be considered if it is practicable to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

ADDRESSES: A copy of the petition for rulemaking is available for public inspection and copying at the Commission's Public Document Room, 1717 H Street NW, Washington, DC 20555.

All persons who desire to submit written comments concerning the petition for rulemaking should send their comments to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

FOR FURTHER INFORMATION CONTACT: John Philips, Chief, Rules and Procedures Branch, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: 301-492-7086.

SUPPLEMENTARY INFORMATION:

I. Background

The petitioner states that the Federal Advisory Committee Act (the Act) mandates that all advisory committee meetings shall be open to the Public (5 U.S.C. App. I, § 10(a)(1)). This general requirement of open deliberations is subject only to the limited exceptions contained in the Government in the Sunshine Act (5 U.S.C. 552b(c)), which were made applicable to the Act through a 1976 amendment. Further, when discussions fall within the scope of an exemption, closing the meeting to the public is not mandatory but only permissive. This was Congress's intention to create a presumption in favor of openness so that the burden of proof was placed on the agencies covered to sustain their decisions to close meetings to public observation. The petitioner states that the Act mandates that either the President or the head of the agency to which the advisory committee reports should determine when meetings or portions thereof may justifiably be closed to the public (5 U.S.C. App. I § 10(d)). The Act contains no specific authorization for delegation of this responsibility. The Act does, however, specifically authorize the delegation of certain responsibilities under the Act, including Freedom of Information Act determinations, to a designated Federal Advisory Committee Management Officer (5 U.S.C. App. I, § 8(b)). At least arguably, this tends to indicate that Congress did not intend that advisory committee meeting closure decisions should be delegable.

II. NRC Practice

The petitioner states that at the present time, the Commission has delegated the responsibility for making closed meeting determinations to the Assistant Secretary (NRC Manual Chapter 0105-033(b)). The current Advisory Committee Management Officer has advised the petitioner that the authority for this delegation derives for 5 U.S.C. App. I, § 8 and 10 CFR 7.5. However, neither of these provisions specifically refers to the authority to make closure determinations and the language of the manual provision in question and 10 CFR 7.9(d) appear to the petitioner to be limited solely to initial closure decisions. Neither makes any mention of authority to rule on petitions for reconsideration.

The present practice regarding advisory committee closure contains none of the safeguards to ensure adequate consideration of the public interest which exist pertaining to the Commission's own meetings. The Commission, according to the petitioner, rejected proposals to adopt a formal two-step meeting closure procedure in reliance on the awareness of the Commissioners and their advisors of countervailing public interest concerns. The petitioner further states that the present lack of involvement on the part of the Commissioners themselves regarding advisory committee closure determinations increases the possibility that the public interest in open deliberations will not receive adequate consideration.

The petitioner asserts that the Commission, as the collegial body heading the NRC, should retain the ultimate responsibility for reviewing the decisions of its delegate. The clear import of the Act, maintains the petitioner, mandates that the Commission should exercise the authority to review the closure decisions of its delegate when they are challenged. The petitioner states that providing for review of the delegate's determinations by the General Counsel is not sufficient to discharge the statutory responsibility imposed on the Commissioners themselves.

III. Proposed Amendment of 10 CFR 7.9

In order to establish a procedure for seeking reconsideration of decisions to close advisory committee meetings, in whole or in part, to public observation and participation, the petitioner recommends the following amendments to the regulations.

1. Present paragraph (e) of 10 CFR 7.9 would be redesignated as paragraph (g).

2. New paragraph (e) and (f) would be added to 10 CFR 7.9 to read as follows:

(e) Any person may petition the

Commission to reconsider its action under § 7.9(c) or the action of its delegate under § 7.9(d) by filing a petition for reconsideration with the Commission within seven days after the date of public announcement of such action and before the meeting in question is held.

(f) A petition for reconsideration filed pursuant to paragraph (e) of this section shall state specifically the grounds on which the action of the Commission or its delegate is claimed to be erroneous, and shall set forth, if appropriate, the public interest in the opening of the meeting. The filing of such a petition shall not act to stay the effectiveness of the action of the Commission or its delegate or to postpone or delay the meeting in question unless the Commission orders otherwise.

The petitioner points out that the proposed new paragraphs (e) and (f) establish a clear procedure for reconsideration of advisory committee meeting closure decisions similar to that available for review of decisions to close Commission meetings pursuant to 10 CFR 9.106 (b) and (c). With several exceptions, the language of the proposed amendments is identical to that employed in § 9.106.

In proposed new paragraph (e), the petitioner has also specified that a petition for reconsideration may be filed within seven days of public announcement of the closure decision. The petitioner believes that allowing at least seven days after the public announcement rather than the date of the decision itself, as is the case with 10 CFR 9.106(b), is required because Part 7 contains no provision comparable to § 9.105(b) requiring prompt public notification of the closure decision.

The petitioner believes that the proposed amendments will adequately address the concerns raised in his petition without unduly burdening the Commission. Moreover, the petitioner concludes that providing an established mechanism to invoke Commission review of advisory committee closure determinations should enhance the probability that the Commission's delegate will give adequate attention to the public interest in open deliberations when making his decisions.

Dated at Washington, DC this 23rd day of October 1984.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

PART 7

ADVISORY COMMITTEES

STATEMENTS OF CONSIDERATION

40 FR 8774
Published 3/3/75
Effective 3/3/75

Energy Reorganization Act; Revision to Chapter 1 to Reflect Organizational and Procedural Changes

See Part 2 Statements of Consideration.

41 FR 55851
Published 12/23/76
Effective 12/23/76

Advisory Committees; Standards for Protection Against Radiation; Physical Protection of Plants and Materials

The amendments of Appendix D of 10 CFR Part 20 and Appendix A of 10 CFR Part 73 set forth below change the telephone number for daytime and nights and holidays of the Region II Inspection and Enforcement Office and change the suite number from 818 to 1217.

Section 7.13 of 10 CFR Part 7 currently refers to "the actual cost of duplication prescribed in § 9.9 of this chapter." The amendment of § 7.13 set forth below changes this reference to "the actual cost of duplication prescribed in Part 9 of this chapter."

Because these amendments relate solely to corrections and minor matters the Commission has found that good cause exists for omitting notice of proposed rule making, and public procedure thereon, as unnecessary and for making the amendments effective on December 23, 1976.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments of Title 10, Chapter I, Code of Federal Regulations, Parts 7, 20, and 73 are published as a document subject to codification.

42 FR 12875
Published 3/7/77
Effective 3/12/77

Rules Governing Public Attendance at Meetings of the Nuclear Regulatory Commission

See Part 9 Statements of Consideration.

PART 8

INTERPRETATIONS

Sec.
8.1 Interpretation of section 152 of the Atomic Energy Act of 1954; opinion of the General Counsel.
8.2 Interpretation of Price-Anderson Act, section 170 of the Atomic Energy Act of 1954.
8.3 [Reserved]
8.4 Interpretation by the General Counsel: AEC jurisdiction over nuclear facilities and materials under the Atomic Energy Act.
8.5 Interpretation by the General Counsel of § 73.55 of this chapter: Illumination and Physical Search Requirements.

§ 8.1 Interpretation of section 152 of the Atomic Energy Act of 1954; opinion of the General Counsel.

(a) Inquiries have been received as to the applicability of the provisions of section 152 of the Atomic Energy Act of 1954 (68 Stat. 944) to inventions or discoveries made or conceived in the course of activities under licenses issued by the Atomic Energy Commission.

(b) In my opinion a license issued by the Atomic Energy Commission is not a "contract, subcontract, arrangement or other relationship with the Commission" as those terms are used in section 152 of the act. Hence, the mere fact that an invention or discovery is made by a licensee in the course of activities authorized by a license would not give the Commission rights under section 152 with respect to such invention or discovery. On the other hand, if a licensee has entered into a "contract, subcontract, arrangement or other relationship with the Commission," inventions or discoveries made or conceived by the licensee under the contract or other relationship would come within the purview of section 152.

(c) As used in this section "license" means a license issued pursuant to Chapter 6 (Special Nuclear Material), 7 (Source Material), 8 (Byproduct Material) or 10 (Atomic Energy Licenses) of the Atomic Energy Act of 1954, or a construction permit issued pursuant to section 185 of the act.

21 FR 1414

§ 8.2 Interpretation of Price-Anderson Act, section 170 of the Atomic Energy Act of 1954.

(a) It is my opinion that an indemnity agreement entered into by the Atomic Energy Commission under the authority of the Atomic Energy Act of 1954 (42 U.S.C. § 2011, et seq.), hereafter cited as "the Act," as amended by Public Law 85-256 (the "Price-Anderson Act") (42 U.S.C. § 2210) indemnifies persons indemnified against public liability for bodily injury, sickness, disease or death, or loss of or damage to property, or for loss of use of property caused outside the United States by a nuclear incident occurring within the United States.

(b) Section 170 authorizes the Commission to indemnify against "public liability" as defined in section 11(u) of the Act.[1] Coverage under the Act therefore is predicted upon "public liability," and requires (1) "legal liability" for (2) a "nuclear incident." Determination of the Act's coverage, therefore, necessitates a finding that these two elements are present.

(c) In the case of damage outside of the United States caused by a nuclear facility based in the United States there would be a "nuclear incident" as defined in section 11(o) since there would be an "occurrence within the United States causing * * * damage."[2] The "occurrence" would be "within the United States" since "occurrence" is intended by the Act to be "that event at the site of the licensed activity * * * which may cause damage rather than the site where the damage may perhaps be caused." S. Rep. 296, 85th Cong., 1st Sess., p. 16 (1957) (hereafter cited as Report). In Section 11(o) an "occurrence" is that which causes damage. It would be, therefore, an event taking place at the site. This definition of "occurrence" is referred to in the Report at page 22 and is crucial to the Act's placing of venue under section 170(e).[3] In its definition of "nuclear incident," the Act makes no limitation upon the place where the damage is received but states only that the "occurrence" must be within the United States.

(d) Similarly, the requirement of "legal liability" would be met. The words of the Act impose no limitation that the liability be one for damage caused in the United States but, on the contrary, are exceedingly broad permitting indemnification for "any legal liability." In the most exhaustive study of the subject, it is stated that the phrase "any legal liability"

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[1] Sec. 11u. "The term 'public liability' means any legal liability arising out of or resulting from a nuclear incident, except claims under State or Federal Workmen's Compensation Acts of employees of persons idemnified who are employed at the site of and in connection with the activity where the nuclear incident occurs, and except for claims arising out of an act of war. 'Public Liability' also includes damage to property of persons indemnified: *Provided*, That such property is covered under the terms of the financial protection required, except property which is located at the site of and used in connection with the activity where the nuclear incident occurs."

[2] Sec. 11o. "The term 'nuclear incident' means any occurrence within the United States causing bodily injury, sickness, disease, or death or loss of or damage to property, or for loss of use of property, arising out of or resulting from the radioactive, toxic, explosive, or other hazardous properties of source, special nuclear, or byproduct material: * * *"

[3] "In order to provide a framework for establishing the limitation of liability, the Commission or any person indemnified is permitted to apply to the appropriate district court of the United States which has venue in bankruptcy matters over the site of the nuclear incident. Again it should be pointed out that the site is where the occurrence takes place which gives rise to the liability, not the place where the damage may be caused * * *." Report, p. 22.

indicates that liability for damage outside the United States is covered by the Act. Atomic Industrial Forum, Financial Protection Against Atomic Hazards 61 n. 355 (1957).

(e) Thus the precise language of the Act provides coverage for damage ensuing both within and without the United States arising out of an occurrence within the United States. There would be no occasion for doubt were it not for a single statement contained in the Report of the Joint Committee on Atomic Energy on the Price-Anderson Act. The Report states, at p. 16 that "[i]f there is anything from a nuclear incident at the licensed activity which causes injury abroad, or if there is any activity abroad which causes further injury in the United States the situation will require further investigation at that time." This sentence follows an explicit and lengthy statement that the "occurrence" is an event at the site of the activity:

> * * * The occurrence which is the subject of this definition is that event at the site of the licensed activity, or activity for which the Commission has entered into a contract, which may cause damage, rather than the site where the damage may perhaps be caused. This site must be within the United States. The suggested exclusion of facilities under license for export was not accepted. This is because the definition of "nuclear incident" limits the occurrence causing damage to one within the United States. It does not matter what license may be applicable if the occurrence is within the United States. If there is anything from a nuclear incident at the licensed activity which causes injury abroad or if there is any activity abraod which causes further injury in the United States the situation will require further investigation by the Congress at that time * * *

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Read literally, the last sentence would seem inconsistent with the preceding statement. It is, however, possible to read the sentence as consistent with the preceding statement if it is taken as indicating a recognition by Congress of the fact that the statutory limitation of liability to $500,000,000 would probably not limit claims by foreign residents to that amount in foreign courts and that therefore the persons indemnified were not fully protected against bankrupting claims, one of the primary purposes of the bill.[4]

(f) The point in question received scant attention during the hearings preceding adoption of the bill held by the Joint Committee on Atomic Energy. A summary of the study of the Atomic Industrial Forum, cited above, was introduced into the record of the hearing and included a conclusion that the provisions of the bill seemed to cover the situation.[5] That conclusion would seem entitled to more than ordinary weight since the Forum study received the careful consideration of the Joint Committee,[6] and the study referenced a statement from the 1956 Report very similar to the confusing statement in the 1957 Report noted above.[7]

(g) There was also a rather ambiguous colloquy in the hearings between Representative Cole and Mr. Charles Haugh in which Representative Cole indicated that the Joint Committee "* * * will do pretty well if we successfully protect the American people and property owners in this country without worrying about those that live abroad."[8]

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(h) Congress, in enacting the Price-Anderson Indemnity Act added to section 2 of the Atomic Energy Act of 1954, a new subsection which stated, inter alia:

> In order * * * to encourage the development of the atomic energy industry, * * * the United States may make funds available for a portion of the damages suffered by the public from nuclear incidents, and may limit the liability of those persons liable for such losses.

This statutory purpose is frustrated if the atomic energy industry is not protected from bankrupting liabilities for damages caused abroad by an accident occurring in the United States.[9] In the Report, the Joint Committee on Atomic Energy made explicit mention of the fact that the private insurance to be provided for reactor operators included coverage for damage in Canada and Mexico and, at another point, noted the Committee's hope that the insurance contract in its final form would cover the same scope as the bill.[10]

(i) It is my opinion that since the language of the Act draws no distinction between damage received in the United States and that received abroad, none can properly be drawn. To read the Act as imposing such a limitation in the absence of statutory direction and in the light of an avowed Congressional intention to encourage the development of the atomic energy industry would be unwarranted. The confusing sentence cited in the Report must, therefore, be read consistently with the language of the Act in the manner suggested above, i.e., as recognizing Congressional inability to limit foreign liability, or must be ignored as inconsistent with the broad coverage of the statutory language.

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§ 8.3 [Deleted 43 FR 17798.]

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[4] Atomic Industrial Forum, Financial Protection Against Atomic Hazards, The International Aspects, p.52 (1959)

[5] Hearings before the Joint Committee on Atomic Energy, Governmental Indemnity and Reactor Safety, 85th Cong., 1st Sess., p. 181 (1957) (hereinafter referred to as "Hearings.")

[6] Hearings, p. 168.

[7] Hearings, p. 182.

[8] Hearings, p. 97. It is significant to note that Mr. Haugh stated at that point the problem of the reactor operator who is concerned with any type of liability. He noted that the insurance contracts would cover "* * * the instance where * * * something happen[ed] out of the country and a suit is brought in the United States on that."

[9] The Atomic Industrial Forum study notes that "[T]o be adequate, the governmental indemnity must cover industry's liability to residents of the countries who suffer as a result of an accident at an installation based in the United States." p. 61. This is certainly the case and one of the major Congressional purposes is frustrated should the Act be said to be unclear on this point. The principal reason for the conclusion that there is coverage reached in the Forum study is the fact that Price-Anderson provides indemnity for "any legal liability." Arthur Murphy, Director of the study, in a recent article, has stated that the confusing sentence in the Report is "* * * inconsistent with the flat coverage of anylegal liability by the idemnity." Murphy, Liability for Atomic Accidents and Insurance, in Law and Administration in Nuclear Energy 75 (1959). In the testimony before the Joint Committee last year, Professor Samuel D. Estep, one of three authors of the comprehensive study of Atoms and the Law apparently relying upon the legislative history, stated that the problem of a reactor accident in the United States causing damage in a foreign country was unclear, presumably since he considered the phrase "any legal liability" directed at a different problem. Hearings before the Joint Committee on Atomic Energy, Idemnity and Reactor Safety, 86th Cong., 1st Sess., p. 77 (1959); Stason Estep, and Pierce, Atoms and the Law, 577 (1959). Professor Estep stated that there "surely ought to be" coverage and suggested a clarifying amendment. His statement that the phrase "any legal liability" covers only the question of time restrictions for claims seems to me erroneous since the language used, "any legal liability," seems intentionally broad. Additionally, should this very narrow reading be given to admittedly broad statutory language, the Congressional purpose would be frustrated.

[10] Report, p.11.

§ 8.4 Interpretation by the General Counsel: AEC jurisdiction ower nuclear facilities and materials under the Atomic Energy Act.

(a) By virtue of the Atomic Energy Act of 1954, as amended,[11] the individual States may not, in the absence of an agreement with the Atomic Energy Commission, regulate the materials described in the Act from the standpoint of radiological health and safety. Even States which have entered into agreements with the AEC lack authority to regulate the facilities described in the Act, including nuclear power plants and the discharge of effluents from such facilities, from the standpoint of radiological health and safety.

(b) The Atomic Energy Act of 1954 sets out a pattern for licensing and regulation of certain nuclear materials and facilities on the basis of the common defense and security and radiological health and safety. The regulatory pattern requires, in general, that the construction and operation of production facilities (nuclear reactors used for production and separation of plutonium or uranium-233 or fuel reprocessing plants) and utilization facilities (nuclear reactors used for production of power, medical therapy, research, and testing) and the possession and use of byproduct material (radioisotopes), source material (thorium and uranium ores), and special nuclear material (enriched uranium and plutonium, used as fuel in nuclear reactors), be licensed and regulated by the Commission.[12] In carrying out its statutory responsibilities for the protection of the public health and safety from radiation hazards and for the promotion of the common defense and security, the AEC has promulgated regulations which establish requirements for the issuance of licenses (Parts 30-36, 40, 50, 70, 71, and 100 of this chapter) and specify standards for radiation protection (Part 20 of this chapter).

(c) The Atomic Energy Act of 1954 had the effect of preempting to the Federal Government the field of regulation of nuclear facilities and byproduct, source, and special nuclear material. Whatever doubts may have existed as to that preemption were settled by the passage of the Federal-State amendment to the Atomic Energy Act of 1954 in 1959.[13]

(d) Prior to 1954, all nuclear facilities and the special nuclear material produced by or used in them were owned by the AEC.[14] This Federal monopoly of atomic energy activities was due in large part to the use of atomic energy materials and facilities in our national weapons program, and the large capital investment required for their development. The Atomic Energy Act of 1954 permitted private ownership of nuclear facilities for the first time, but only under a comprehensive, pervasive system of Federal regulation and licensing. That Act recognized no State responsibility or authority over such facilities and materials except the States' traditional regulatory authority over generation, sale, and transmission of electric power produced through the use of nuclear facilities.[15] As interest grew in the private construction of facilities and the use of atomic energy materials, and the numbers of persons qualified in the field increased, questions arose as to the role State authorities should play with regard to the public health and safety aspects of such activities. Several bills were introduced with respect to Federal-State cooperation in 1956 and 1957.[16] An AEC proposed bill which would have authorized concurrent radiation safety standards to be enforced by the States was forwarded to the Joint Committee on Atomic Energy in 1957, but was never reported out. Finally, in 1959, legislation was enacted whose purpose was to promote an orderly regulatory pattern between the Federal and State governments with respect to regulation of byproduct, source, and special nuclear material, while avoiding dual regulation (see section 274a). That legislation added section 274, the so-called Federal-State amendment, to the Atomic Energy Act.

(e) Section 274 (42 U.S.C. 2021) authorizes the Commission to enter into an agreement with the Governor of any State providing for the discontinuance of regulatory authority of the Commission with respect to byproduct materials, source materials, and special nuclear materials in quantities not sufficient to form a "critical mass." However, section 274c (42 U.S.C. 2021 (c)) provides that the Commission shall retain authority and responsibility with respect to the regulation of:

(1) The construction and operation of production or utilization facilities (note: this includes construction and operation of nuclear powerplants);

(2) The export and import of byproduct, source or special nuclear material or production or utilization facilities;

(3) The disposal into the ocean of waste byproduct, source or special nuclear materials; and

(4) The disposal of such other byproduct, source or special nuclear material as the Commission determines should, because of the hazards or potential hazards thereof, not be so disposed of without a Commission license.

(f) The amendment, in providing for the discontinuance of some of the AEC's regulatory authority over source, byproduct and special nuclear material in States which entered into agreements with the AEC, made clear that there should be no "dual regulation" with respect to those materials for the purpose of protection of the public health and safety from radiation hazards.

(g) Section 274b of the Atomic Energy Act (42 U.S.C. 2021 (b)) states that:

> During the duration of such an agreement it is recognized that the State shall have authority to regulate the materials covered by the agreement for the protection of the public health and safety from radiation hazards.

Section 274k (42 U.S.C. 2021 (k)) states:

> Nothing in this section shall be construed to affect the authority of any State or local agency to regulate activities for purposes other than protection against radiation hazards.

(h) In its comments on the bill that was enacted as section 274, the Joint Committee on Atomic Energy commented that:

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[11] Public Law 83-703, 68 Stat. 919.

[12] The terms "byproduct material," "source material," and "special nuclear material" are defined in the Atomic Energy Act, sections 11e, 11z, and 11aa, respectively. The terms "production facility" and "utilization facility" are defined in sections 11v and 11cc of the Act, respectively.

[13] Public Law 86-373, 73 Stat. 688.

[14] Atomic Energy Act of 1946, Public Law 79-585, 60 Stat. 755.

[15] Section 271, 42 U.S.C. 2018.

[16] S. 4298 and H.R. 8676, 84th Cong., second session; S. 53, 85th Cong., first session.

> It is not intended to leave any room for the exercise of dual or concurrent jurisdiction by States to control radiation hazards by regulating byproduct, source, or special nuclear materials. The intent is to have the material regulated and licensed either by the Commission, or by the State and local governments, but not by both.[17]

In explaining section 274k, the Joint Committee said:

> As indicated elsewhere, the Commission has exclusive authority to regulate for protection against radiation hazards until such time as the State enters into an agreement with the Commission to assume such responsibility.[18]

(i) It seems completely clear that the Congress, in enacting section 274, intended to preempt to the Federal Government the total responsibility and authority for regulating, from the standpoint of radiological health and safety, the specified nuclear facilities and materials; that it stated that intent unequivocally; and that the enactment of section 274 effectively carried out the Congressional intent, subject to the arrangement for limited relinquishment of AEC's regulatory authority and assumption thereof by states in areas permitted, and subject to conditions imposed, by section 274.[19]

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(j) Thus, under the pattern of the Atomic Energy Act, as amended by section 274, States which have not entered into a section 274 agreement with the AEC are without authority to license or regulate, from the standpoint of radiological health and safety, byproduct, source, and special nuclear material or production and utilization facilities. Even those States which have entered into a section 274 agreement with the AEC (Agreement States) lack authority to license or regulate, from the standpoint of radiological health and safety, the construction and operation of production and utilization facilities (including nuclear power plants) and other activiteis reserved to the AEC by section 274c. (To the extent that Agreement States have authority to regulate byproduct, source, and special nuclear material, their section 274 Agreements require them to use their best efforts to assure that their regulatory programs for protection against radiation hazards will continue to be compatible with the AEC's program for the regulation of byproduct, source and special nuclear material.)

(k) The following judicial precedents and legal authorities support the foregoing conclusions: Northern California Ass'n, Etc. v. Public Utilities Commission, 37 Cal. Rep. 432, 390 P. 2d 200 (1964); Boswell v. City of Long Beach, CCH Atomic Energy Law Reports, par. 4045 (1960); Opinion of the Attorney General of Michigan (Oct. 31, 1962); Opinion of the Attorney General of South Dakota (July 23, 1964); New York State Bar Association, Committee on Atomic Energy, State Jurisdiction to Regulate Atomic Activities (July 12, 1963). No precedents or authorities to the contrary have come to our attention.

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§ 8.5 Interpretation by the General Counsel of § 73.55 of this Chapter. Illumination and Physical Search Requirements.

(a) A request has been received to interpret 10 CFR 73.55(c)(5) and 73.55(d)(1).

10 CFR 73.55(c)(5) provides:

> Isolation zones and all exterior areas within the protected area shall be provided with illumination sufficient for the monitoring and observation requirements of paragraphs (c)(3), (c)(4), and (h)(4) of this section, but not less than 0.2 footcandle measured horizontally at ground level.

(b) The requester contends that the regulation is satisfied if 0.2 footcandle is provided only at the protected area boundary and the isolation zone. The language of the regulation is clearly to the contrary. It requires not less than 0.2 footcandle for "all exterior areas within the protected area." This regulation helps effectuate the monitoring and observation requirements of 10 CFR 73.55. For example, 10 CFR 73.55(c)(4) states that "(a)ll exterior areas within the protected area shall be periodically checked to detect the presence of unauthorized persons, vehicles, or materials." In the absence of illumination, such checking could not be fully effective.

(c) The requester also asks whether the illumination requirement extends to the tops and sides of buildings within the protected area. To effectuate the monitoring and observation requirements cited above, illumination must be maintained for the tops and sides of all accessible structures within the protected area. This interpretation is consistent with that given by the Commission's staff to affected licensees and applicants at a series of regional meetings held in March of 1977 and will be reflected in forthcoming revisions to NUREG 0220, Draft Interim Acceptance Criteria for Physical Security Plan for Nuclear Power Plants (March 1977).

(d) 10 CFR 73.55(d)(1) provides in pertinent part: The search function for detection of firearms, explosives, and incendiary devices shall be conducted either by a physical search or by use of equipment capable of detecting such devices.

(e) The requestor contends that until "equipment capable of detecting such devices" is in place, a licensee need not comply with the search requirement, but can utilize instead previous security programs. This contention is based on the first sentence of 10 CFR 73.55 which provides in pertinent part that the requirements of paragraph (d) of that section shall be met by May 25, 1977, "except for any requirement involving construction and installation of equipment not already in place expressed in (paragraph)(d)(1) * * *" Under this sentence only those requirements of paragraph (d) which involve "construction and installation of equipment" do not take effect on May 25, 1977. Because a "physical search" does not require "construction and installation of equipment", implementation of such searches is required on May 25, 1977. The regulation provides alternatives: "the search function * * * shall be conducted either by a physical search or by use of equipment * * *." Thus when appropriate equipment is in place, the search function need not involve a physical search.

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(f) The paragraphs above set forth interpretation of regulations; they do not apply those regulations to particular factual settings. For example, no effort is made to state what lighting system might be used for a given facility; all that is stated is that a system must provide not less that 0.2 footcandle for all exterior

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[17] 1959 U.S. Code Congressional and Administrative News, v.2, p. 2879.

[18] Id. at pp. 2882-3.

[19] As noted above, regulation of construction and operation of production or utilization facilities was one of the areas reserved to the AEC. It is clear from the legislative history of section 274 that control of "operation" of such facilities includes the regulation of the radiological effects of the discharge of effluents from the facilities. (Hearings before the Joint Committee on Atomic Energy on Federal-State Relationships in the Atomic Energy Field, 86th Cong., first session, 1959, p. 306.) AEC regulations implementing section 274 recognize that intent by defining facility operation to include the discharge of radioactive effluents from the facility site (10 CFR 150.15).:

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areas within the protected area. Similarly, no effort is made to define what is an adequate "physical search"; all that is stated is that, in the absence of appropriate equipment, such searches must begin on May 25, 1977.

PART 8

INTERPRETATIONS

STATEMENTS OF CONSIDERATION

21 FR 1414
Published 3/3/56

A new part is hereby added to the regulations in Title 10, Chapter 1, CFR, to contain interpretations of the Atomic Energy Act of 1954 (68 Stat. 919) and of regulations of the Atomic Energy Commission issued thereunder.

32 FR 11379
Published 8/5/67
Effective 8/5/67

Computation of Time

See Part 2 Statements of Consideration.

34 FR 7273
Published 5/3/69
Effective 5/3/69

An interpretation by the General Counsel of the Atomic Energy Commission of the Atomic Energy Act of 1954, as amended, is added to the Atomic Energy Commission's regulation 10 CFR Part 8, which contains interpretations of the Atomic Energy Act of 1954 (68 Stat. 919) and of regulations of the Commission issued thereunder.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendment of 10 CFR Part 8 is published as a document subject to codification, to be effective upon publication in the Federal Register

42 FR 33264
Published 6/30/77
Effective 6/30/77

PART 8—INTERPRETATIONS

Interpretation by the General Counsel of 10 CFR 73.55. Illumination and Physical Search Requirements

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission's regulation "Interpretations" is amended by adding an interpretation by the General Counsel of the requirements for physical protection of licensed activities in nuclear power reactors against industrial sabotage set out in the Commission's regulation "Physical Protection of Plants and Materials." The interpretation clarifies the illumination and physical search requirements of the regulation.

EFFECTIVE DATE: This rule becomes effective on June 30, 1977.

FOR FURTHER INFORMATION CONTACT:

Mr. C. W. Reamer, Office of the General Counsel, Nuclear Regulatory Commission, Washington, D.C. 20555. Tel. 301-492-8155.

SUPPLEMENTARY INFORMATION: Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendment of Title 10, Chapter I, Code of Federal Regulations, Part 8, is published as a document subject to codification.

PART 9

PUBLIC RECORDS

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APPENDIX A—REQUESTS FOR DECLASSIFICATION REVIEW

Authority: Sec. 161, 68 Stat. 948, as amended (42 U.S.C. 2201); sec. 201, 88 Stat 1242, as amended (42 U.S.C. 5841).

Subpart A also issued under 5 U.S.C. 552 and 31 U.S.C. 9710. Subpart B also issued under 5 U.S.C. 552a. Subpart C also issued under 5 U.S.C. 552b. 50 FR 25204

§9.1 Scope.

The regulations in this part implement: (a) The provisions of the Freedom of Information Act, 5 U.S.C. 552, with respect to the availability to the public of Nuclear Regulatory Commission records for inspection and copying; (b) the provisions of the Privacy Act of 1974, Pub. L. 93-579, with respect to disclosure and availability of certain Nuclear Regulatory Commission records maintained on individuals; and (c) the provisions of the Government in the Sunshine Act, 5 U.S.C. 552b, with respect to opening Commission meetings to public observation.

§9.1a Subparts.

Subpart A sets forth special rules applicable to matters pertaining to the Freedom of Information Act. Subpart B sets forth special rules applicable to matters pertaining to the Privacy Act of 1974. Subpart C sets forth special rules applicable to matters pertaining to the Government in the Sunshine Act. 42 FR 12875

§9.2 Definitions.

As used in this part:

(a) "NRC" means the Nuclear Regulatory Commission, established by the Energy Reorganization Act of 1974. 40 FR 44483

(b) "NRC personnel" means employees, consultants, and members of advisory boards, committees and panels of the NRC; members of boards designated by the Commission to preside at adjudicatory proceedings; and officers or employees of Government agencies; including military personnel, assigned to duty at the NRC.

(c) "Commission" means the commission of five members or a quorum thereof sitting as a body, as provided by section 201 of the Energy Reorganization Act of 1974.

(d) "Government agency" means any executive department, military department Government corporation, Government controlled corporation, or other establishment in the executive branch of the Government (including the Executive Office of the President), or any independent regulatory agency.

(e) "Working days" means Monday through Friday, except legal holidays.,

§9.2a Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by an officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

§ 9.2b Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). OMB has approved the information collection requirements contained in this part under control number 3150–0043.

(b) The approved information collection requirements contained in this part appear in §§ 9.14a and 9.14b.

Subpart A—Freedom of Information Act Regulations

§9.3 Scope of subpart.

This subpart prescribes procedures under which NRC records are made available to the public for inspection and copying pursuant to the provisions of 5 U.S.C. 552. This subpart does not affect the dissemination or distribution of NRC originated, or NRC contractor originated, information to the public pursuant to any NRC public, technical, or other information program or policy, nor is it intended to restrict or limit the free flow of information between the NRC and its contractors and subcontractors, or between the NRC and a Government agency. Except where specifically noted otherwise, this subpart applies to all records whether they predate or postdate July 4, 1967.

§ 9.3a Definitions.

As used in this subpart:

(a) "Office", unless otherwise indicated, means all offices and divisions of the NRC reporting to or through the Executive Director for Operations, except for the Office of the Executive Legal Director.

(b) "Record" means any book, paper, map, photograph, brochure, punch card, magnetic tape, paper tape, sound recording, pamphlet, slide, motion picture, or other documentary material regardless of form or characteristics, made by, in the possession of, or under the control of the NRC pursuant to Federal law or in connection with the transaction of public business as evidence of NRC organization, functions, policies, decisions, procedures, operations, programs or other activities. "Records" do not include objects or articles such as structures, furniture, tangible exhibits or models, or vehicles and equipment.

§ 9.4 Availability of records.

Any identifiable record, whether in the possession of the NRC, its contractors, its sub contractors, or others, shall be made available for inspection and copying pursuant to the provisions of this part, upon request of any member of the public.

§ 9.5 Exemptions.

(a) The following types of records are exempt from public disclosure under § 9.4:

(1) Records (i) which are specifically authorized under criteria established by an Executive order to be kept secret in the interest of national defense or foreign policy, and (ii) which are in fact properly classified pursuant to such Executive order.

(2) Records related solely to the internal personnel rules and practices of the NRC. This exemption does not apply to rules relating to the work hours, leave, and working conditions of NRC personnel, or similar matters. To the extent that they cannot be disclosed without harm to the functions to which they pertain, examples of exempt records of the type specified in the first sentence of this paragraph include, but are not limited to:

(i) Operating rules, guidelines, manuals on internal procedure, schedules and methods utilized by NRC inspectors, investigators, auditors, and examiners;

(ii) Bargaining positions and limitations involved in a negotiation prior to the execution of a contract or the completion of the action to which the bargaining positions or limitations were applicable except as they may be exempt pursuant to other provisions of this section.

(iii) Personnel policies, procedures and instructions; internal staffing plans, requirements, authorizations, controls, and supporting data relating to position management and manpower utilization; and information involved in the determination of the qualifications of candidates for employment or advancement.

(3) records specifically exempted from disclosure by statute (other than 5 U.S.C. 552(b)), provided that such statute (i) requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue, or (ii) establishes particular criteria for withholding or refers to particular types of matters to be withheld.

(4) Trade secrets and commercial or financial information obtained from a person and privileged or confidential. Matter subject to this exemption is that which is customarily held in confidence by the originator. It includes, but is not limited to:

(i) Information received in confidence, such as trade secrets, inventions and discoveries, and proprietary data;

(ii) Technical reports and data, designs, drawings, specifications, formulae, or other types of proprietary information which are generated or developed by the NRC or for the NRC under contract;

(iii) Statistical data or information concerning contract performance, income, profits, losses, and expenditures, if received in confidence from a contractor or potential contractor;

(iv) [Deleted 40 FR 8774.]

(5) Interagency or intraagency memorandums or letters which would not be available by law to a private party in litigation with the NRC. To the extent not so available by law, examples include, but are not limited to:

(i) Reports, memorandums, letters, correspondence, work papers, minutes of meetings, and staff papers prepared for use within the NRC or within the Executive Branch of the Government by *(a)* members of the Commission, NRC personnel, or any Government agency, or *(b)* an NRC contractor, or its personnel acting within the scope of a contract with the NRC;

(ii) Advance information on proposed NRC plans to procure, lease or otherwise acquire or dispose of materials, real estate, facilities, or functions, when such information would provide undue or unfair competitive advantage to any person;

(iii) Records prepared for use in proceedings before any Federal or State court or administrative body;

(iv) Evaluations of contractors or products;

(v) Information scheduled for public release, but as to which premature release would be contrary to the public interest, such as documents awaiting patent review;

(vi) Reports of inspections or investigations or surveys which pertain to the internal management or administration of the NRC;

(vii) Financial accounts and records and supporting documents; budget documents and supporting papers used or arising in the preparation and/or execution of a budget; annual and multiyear program and financial plans and support papers; audit reports, programs, work papers, and other data developed during the course of audits.

(6) Personnel and medical files and similar files, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. Information in such files which is not exempt from disclosure pursuant to other provisions of this section will not be withheld from the individual concerned or from his designated legal representative, and it may be disclosed to others with his written consent. To the extent that they involve a clearly unwarranted invasion of personal privacy, examples of files exempt from disclosure include, but are not limited to:

(i) Files containing the names of individuals who have received exposure to radiation;

(ii) Files containing reports, records and other material pertaining to individual cases in which disciplinary or other administrative action has been or may be taken, including records of proceedings pertaining to the conduct or performance of duties by NRC personnel. Opinions and orders resulting from those proceedings shall be disclosed without identifying details if used, cited or relied upon as precedent, as provided in §9.6.

(7) Investigatory records compiled for law enforcement purposes, but only to the extent that the production of such records would (i) interfere with enforcement proceedings, (ii) deprive a person of a right to a fair trial or an impartial adjudication, (iii) constitute an unwarranted invasion of personal privacy, (iv) disclose the identity of a confidential source and, in the case of a record compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, confidential information furnished only by the confidential source, (v) disclose investigative techniques and procedures or (vi) endanger the life or physical safety of law enforcement personnel.

(8) Matters contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of any Government agency responsible for the regulation or supervision of financial institutions.

(9) Geological and geophysical information and data (including maps) concerning wells.

(b) Any reasonably segregable portion of a record shall be provided to any person requesting such record after deletion of the portions which are exempt under this section.

(c) If a requested record is one of another Government agency or deals with subject matter as to which a Government agency other than the NRC has exclusive or primary responsibility, the request for such a record shall be promptly referred by the NRC to that Government agency for disposition or for guidance with respect to disposition.

(d) Nothing in this part authorizes withholding of information or limiting the availability of records to the public, except as specifically provided in this part, nor is this part authority to withhold information from Congress.

§9.6 Deletion of identifying details.

Whenever the release of the name or names or other identifying details of, or relating to, a private party or parties will constitute a clearly unwarranted invasion of personal privacy, an opinion, order, or other record required to be made available pursuant to 5 U.S.C. section 552 will be published or made available with such identifying details deleted and with a notification such as the following as a preamble:

Names of parties and certain other identifying details have been removed in order to prevent a clearly unwarranted invasion of the personal privacy of the individuals involved.

§9.7 Publicly available records.

(a) The NRC Public Document Room is located at 1717 H Street, N.W., Washington, D.C., and is open between 8:30 a.m. and 5:00 p.m. on Monday through Friday, except legal holidays. The following records or documents are available at the NRC Public Document Room for public inspection and copying:

(1) Final opinions including concurring and dissenting opinions as well as orders of the NRC made in the adjudication of cases;

(2) Statements of policy and interpretations which have been adopted by the NRC and have not been published in the FEDERAL REGISTER;

(3) A record of the final votes of each member of the Commission in every proceeding;

(4) Nuclear Regulatory Commission rules and regulations;

(5) Nuclear Regulatory Commission Manual and instructions to NRC personnel that affect any member of the public;

(6) Current indexes of the foregoing records issued, adopted or promulgated after July 4, 1967.

(b) The NRC will publish, quarterly or more frequently, and distribute (by sale or otherwise) copies of the indexes or supplements thereto, specified in paragraph (a) (6) of this section, unless it determines by order published in the FEDERAL REGISTER that publication would be unnecessary and impracticable, in which case the NRC will provide copies of such indexes on request at a cost not to exceed the direct cost of reproduction as provided in §9.14.

§9.8 Requests for records.

(a) Copies of records may be requested in person at the NRC Public Document Room, 1717 H Street, N.W., Washington, D.C. Written requests for copies of records shall be addressed to the Director, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

The request should clearly state on the envelope and in the letter that it is a "Freedom of Information Act request".

A request that is not so marked will be deemed not to have been received by the NRC until it is actually received by the Director, Office of Administration.

(b) All requests for copies of records must reasonably describe the record sought in sufficient detail to permit the identification of the requested record. Where possible, specific information regarding dates, titles, docket numbers, file designations, and other information which may help identify the records should be supplied by the requester. If a request does not reasonably describe the record sought in sufficient detail to permit its identification, the requester will be so informed by the Director, Office of Administration, or his designee, within 10 working days after receipt of the request and requested to submit additional information regarding the request or to meet with appropriate NRC personnel in order to clarify the request. Requests for Waiver or reduction of fees shall be made in accordance with §9.14a, waiver or reduction of fees, and shall be processed in accordance with §9.14b, Processing of requests for a waiver or reduction of fees.

44 FR 15998

(c) If the record for which a request is made has been reasonably described pursuant to paragraph (b) of this section and is available in the NRC Public Document Room, the requester will be informed within 10 working days after receipt of the request by the Director, Office of Administration, or his designee, of the time and place where the record will be made available, and the estimated cost for furnishing copies of the record. In order to obtain copies of records in the most expeditious manner, a person may request copies of records in person at the NRC Public Document Room, or may open an account at the Public Document Room with the private firm contractually responsible for reproducing copies of NRC records.

40 FR 7893

(d) Requested records which have been reasonably described pursuant to paragraph (b) of this section but which are located at places other than the NRC Public Document Room or NRC headquarters may, at the discretion of the NRC, be made available for inspection and copying at such other locations within 10 working days after receipt of the request. For example, contracting officers may authorize an NRC contractor to disclose records in its possession at the contractor's facility or, if the record is in the possession of a subcontractor, at a subcontractor's facility. To the extent applicable, the charges specified in §9.14 for locating and reproducing copies of records shall be applied to records made available pursuant to this paragraph.

(e) A request for a record which is not available in the NRC Public Document Room shall be promptly forwarded by the Director, Office of Administration, or his designee, to the head of the office primarily concerned with the records requested. The Director, Office of Administration, or his designee will maintain, and the Executive Legal Director or his designee will be furnished, a copy of each request referred to another office, together with the following information: (1) the date the request was received; (2) the office to which it was referred; and (3) the date on which it was referred.

§9.9 Initial determination.

(a) If, after consultation with the Executive Legal Director or his designee, the head of the office to which a request has been referred finds that the record sought is exempt from production or disclosure, but that its production or disclosure is not contrary to the public interest and will not adversely affect the rights of any person, the head of the responsible office will authorize the production or disclosure of the record, and will notify the requester within 10 working days after receipt of the request that the records will be promptly made available.

(b) Except as provided in §9.15, if the head of the office to which a request has been referred finds that a request should be denied in whole or in part, he will submit such findings to the Director, Office of Administration, in sufficient time to comply with the time limits set forth in this paragraph for a response by the Director. The Director, Office of Administration, will, after consultation with the Executive Legal Director or his designee, made an independent determination whether to comply with or deny the request. If the Director, Office of Administration, determines that the record sought is exempt from production or disclosure pursuant to §9.5(a), and its production or disclosure is contrary to the public interest or will adversely affect the rights of any person, the Director, Office of Administration, will notify the requester in the manner provided in §9.10 within 10 working days after receipt of the request.

40 FR 7893

(c) The 10 working day period for response to a request for records provided in paragraphs (a) and (b) of this section may be extended for unusual circumstances as provided in §9.13.

(d) In exceptional circumstances where it does not appear possible to complete action on the request within the maximum 20 working day limit as provided in §9.13, the Director, Office of Administration may seek an agreement with the requester for a specific extension of time in which to act upon the request. Any such agreement shall be confirmed in writing.

(e) If the head of the office to which a request has been referred or the Director, Office of Administration, does not respond to a request within the 10 working day period, or within such extended periods as provided in this Part, the requester may treat such delay as a denial of the request and immediately appeal to the Executive Director for Operations as provided in §9.11(a) or to a district court as provided in §9.11(c).

§9.10 Form and content of responses.

(a) When a requested record has been identified and is available, the head of the office in which a request has been referred or the Director, Office of Administration, will promptly furnish the record or notify the requester as to where and when the record will be available for inspection and copying. Copies of records disclosed in response to Freedom of Information Act requests will normally be placed in the NRC Public Document Room and, in the case of records relating to nuclear power facility, in the Local Public Document Room established for that facility. The notification will also advise the requester of any applicable fees under §9.14.

(b) A reply denying a request for a record or denying a request for waiver or reduction of fees filed pursuant to §9.14a will be in writing signed by the Director, Office of Administration, or his designee, and will include as appropriate:

(1) The reason for the denial;

(2) A reference to the specific exemption under the Freedom of Information Act and the Commission's regulations authorizing the withholding of the record;

(3) The name and title or position of each person responsible for the denial of the request, including the head of the office recommending denial of the request;

(4) A statement as to why the request does not meet the requirements of §9.14a if the request is for a waiver or reduction of fees; and

(5) A statement that the denial may be appealed within 30 days from the receipt thereof to the Executive Director for Operations.

44 FR 15998

(c) A copy of each letter granting or denying requested records or denying a request for waiver or reduction of fees will be maintained by or furnished to the Director, Office of Administration, or his designee.

§9.11 Appeal from initial determination.

(a) Except as provided in §9.15, a requester may within 30 days of receipt of a notice of denial of the request for records or denial of a request for waiver or reduction of fees pursuant to this subpart, appeal such denial to the Executive Director for Operations. The appeal shall be in writing, addressed to the Executive Director for Operations, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and should clearly state on the envelope and in the letter that it is an "Appeal from Initial FOIA Decision." An appeal that is not so marked will be deemed not to have been received by the NRC until it is actually received by the Executive Director for Operations.

(b) Except as provided in §9.13, the Executive Director for Operations will make a determination with respect to any appeal pursuant to this section within 20 working days after the receipt of such appeal.

(c)(1) If on appeal the denial of the request for records is upheld in whole or in part, the Executive Director for Operations will notify the person making such request of the denial, including the exemption relied upon, an explanation of how the exemption applies to the records withheld, and the reasons for asserting the exemption.

(2) If on appeal the denial of a request for waiver or reduction of fees for locating and reproducing records is upheld in whole or in part, the Executive Director for Operations will notify the person making such request of the denial, including a statement as to why the request does not meet the requirements of §9.14a.

(3) The requester shall be informed that the denial is a final agency action and that judicial review is available in a district court of the United States in the district in which the requester resides, or has his principal place of business, or in which the agency records are situated, or in the District of Columbia.

(d) Copies of all appeals and written determinations on appeal will be furnished by the Executive Director for Operations, or his designee, to the Director, Office of Administration, or his designee.

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§9.12 Production or disclosure of exempt records.

(a) Records of the kind specified in §9.5(a) shall not be produced or disclosed by NRC personnel, or NRC contractors who have possession of such records, except in accordance with this Part or §§ 2.744 and 2.790 of this chapter.

(b) NRC personnel and NRC contractors from whom a record exempt from disclosure is sought shall follow the procedure specified below:

(1) If an exempt record is sought from NRC personnel, the request or subpoena shall promptly be forwarded to the Director, Office of Administration, who shall process the request as provided in this Part of take such other action as may be appropriate.

(2) If an exempt record is sought from an NRC contractor, the request or subpoena shall promptly be forwarded to the NRC contracting officer administering the contract who will then follow the procedure specified in paragraph (b)(1) of this section.

(3) NRC personnel or NRC contractors who are required by a subpoena to produce or disclose a record of the types included in §9.5(a) shall appear in response thereto and shall respectfully decline to produce or disclose the record described, basing refusal on this paragraph, unless production or disclosure has been authorized pursuant to this Part.

§9.13 Extension of time for response.

(a) In unusual circumstances specified in paragraph (b) of this section, the time limits prescribed in §9.9 or §9.11 may be extended by not more than 10 working days by written notice to the person making such request, setting forth the reasons for such extension and the date on which a determination is expected to be dispatched.

(b) For purposes of this section, "unusual circumstances" means:

(1) the need to search for and collect the requested records from field facilities or other establishments that are separate from the office processing the request;

(2) the need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records which are demanded in a single request; or

(3) the need for consultation, which shall be conducted with all practicable speed, with another agency having a substantial interest in the determination of the request or among two or more components of the NRC having substantial subject-matter interest therein.

(c) Any extension of time limits prescribed in §§9.9 and 9.11 may not exceed a combined total of 10 working days per request.

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§ 9.14 Charges for production or records.

(a)(1) Charges for the copying of records at the NRC Public Document Room (PDR), 1717 H Street, NW, Washington, DC by the copying service contractor are as follows:

(i) Five cents per page for paper copy to paper copy, except for engineering drawings and any other records larger than 17 x 11 inches for which the charges vary as follows depending on the reproduction process that is used: Xerographic process—$1.25 per square foot for large documents or engineering drawings (random size up to 24 inches in width and with variable length) reduced or full size; Photographic process—$7.00 per square foot for large documents or engineering drawings (random size exceeding 24 inches in width up to a maximum size of 42 inches in length) full size only.

(ii) Five cents per page for microform to paper copy, except for engineering drawings and any other records larger than 17 x 11 inches for which the charge is $1.25 per square foot or $2.60 for a reduced size print (18 x 24 inches).

(iii) Seventy-five cents per microfiche to microfiche.

(iv) One dollar per aperture card to aperture card.

50 FR 25204

(2) Self-service, coin operated, copying machines are available at the PDR for the use of the public. Paper to paper is $0.10 per page. Microform to paper is $0.10 per page on the reader-printers.

(3) Mail order requests for contractor copying of NRC records may be made by writing to the PDR. The charges for mail order reproduction of records are the same as those set out in paragraph (a)(1) of this section, plus mailing or shipping charges.

(4) Accounts can be opened with the copying service contractor. The name and address and billing policy of the contractor can be obtained from the PDR.

(5) Any change in the above costs will become immediately effective for the interim period pending completion of the Commission's rulemaking to establish the new charges.

49 FR 30457

(b) Requests for copies of records to be reproduced and furnished by the NRC at locations other than the NRC Public Document Room located in Washington, D.C., will be honored at the following charges:

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(1) Sizes up to 8½ x 14 inches made on office copying machines—$0.05 per page of copy.

50 FR 25204

READEX FICHE

(2) The charge for reproducing records other than those specified above will be computed on the basis of NRC's direct costs.

(3) If a request is for records at locations other than the NRC Public Document Room, a charge of $5.00 per hour will be made for searching for the requested records by clerical or administrative employees and a charge of $12.00 per hour for searching by professional or supervisory employees.

(4) When a computer search is necessary in order to fulfill a request, the computer search charge will be the actual direct cost of the computer search.

(5) Except as otherwise provided in §9.14a, unless the request specifically states that whatever cost is involved will be acceptable, or acceptable up to a specified limit, the NRC will, for requests involving anticipated costs in excess of the minimum specified in §9.14a(a), so advise the requester as provided in §9.14(b), and the request will not be deemed to have been received until a deposit equal to the estimated costs is received, or the requester has agreed to bear the anticipated costs, or a determination has been made on a request for waiver or reduction of fees. Fees may be required to be paid in full prior to the issuance of the requested records.

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(6) Refunds of unused deposits or additional billings will be made to adjust the anticipated cost to the actual cost.

(c) In compliance with the Federal Advisory Committee Act, transcripts of testimony in NRC proceedings, which are transcribed by a reporting firm under contract with the NRC, may be purchased directly from the reporting firm at the cost of reproduction as provided for in the contract with the reporting firm, or may be purchased from the NRC at the cost of reproduction as provided in paragraphs (a) and (b) of this section.

(d) Copyrighted material will not be reproduced in violation of the copyright laws.

(e) The Director, Office of Administration, or his designee, or the Executive Director for Operations, on appeals, in accordance with the provisions of § 9.14a, will waive or reduce any fee required by this section upon a determination that waiver or reduction of the fee is in the public interest because furnishing the information can be considered as primarily benefiting the general public.

(f) Charges for production of records in Local Public Document Rooms. Charges for the reproduction of NRC documents located in NRC Local Public Document Rooms (LPDRs) may vary according to location.

50 FR 25204

§ 9.14a Waiver or reduction of fees.

(a) Fees for searching and reproduction of records at locations other than the NRC Public Document Room shall be waived:

(1) for search fees when the time for the search does not exceed four hours, in the aggregate, for a request or series of related requests;

(2) where the records are requested by and made available to a Federal, State, or local government, to an intergovernmental agency, or to a foreign government or international agency, and furnishing the records without charge is an appropriate courtesy.

(b) Except as provided in paragraph (a) and (f) of this section, fees for searching and reproduction of records may be waived only upon request. A person requesting the NRC to waive or reduce search or reproduction fees under this subpart shall, as set forth in 9.14b(b), provide sufficient factual information to permit NRC to make the determination whether waiver or reduction of the fee is in the public interest because furnishing the information can be considered as primarily benefiting the general public.

(c) In making a request for waiver or reduction of fees, the requester shall provide a statement setting forth the following information to the extent possible:

44 FR 15998

(1) How the information obtained from the records, or how the conclusions or results from any review or analyses of the records, will be published or otherwise disseminated to the general public;

(2) The size of the public that will be benefited by the disclosure;

(3) The nature, significance and likelihood of any tangible benefit that the public may receive from dissemination of the information;

(4) The financial benefit, if any, the requester will receive from the use of the requested materials;

(5) The ability of the requester to pay for any of the anticipated costs;

(6) How the intended use of the various types of records requested is reasonably likely to:

(i) Result in actions to maintain or enhance the public's health, safety, or the quality of the environment;

(ii) Result in improved regulatory processes;

(iii) Reduce the cost of providing a government service;

(iv) Contribute substantially to public debate on an important policy issue; or

(v) Contribute substantially to matters of historical importance.

(d) Public benefit will not normally result:

(1) When the requested records will be used primarily for the personal benefit of an individual or group rather than the general public;

(2) When the requested records will be used primarily for a commercial purpose or financial benefit;

(3) When the requested records have already been made available, or are being made available in response to the request, for inspection and copying in the NRC Public Document Room or a Local Public Document Room;

(4) When the requested records will not add appreciably to the information already available to the public in the NRC Public Document Room or a Local Public Document Room;

(5) When the requested records consist primarily of technical data which will only be distributed or made available to the public by the requester without further analyses or comment;

(6) When the costs to the public outweigh any benefit which may accrue to the public.

(e) Based upon the information furnished by the requester in response to paragraph (c) and the criteria set forth in paragraph (d) of this section, and the NRC will determine if waiver or reduction of the fee is in the public interest because furnishing the information can be considered as primarily benefiting the general public. In determining whether to waive fees in whole or in part, the NRC will consider the total estimated search and reproduction costs necessary to comply with the request and the extent to which the requester has carried the burden of making the necessary public interest showing under paragraph (c) of this section.

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(f) In the absence of a specific request for waiver or reduction of fees, if the information furnished by the requester is sufficient to meet the requirements of this section for waiver or reduction of fees, NRC may determine that production or disclosure of the requested records can be considered as primarily benefiting the general public.

(g) The NRC will not waive the reproduction costs for documents located or made available in the NRC Public Document Room or a local public document room in the absence of a compelling reason to do so.

§ 9.14b Processing of requests for a waiver or reduction of fees

(a) Within 10 working days after receipt of a request for access to records which does not involve more than four hours of search time, or in which the NRC agrees to waive fees pursuant to § 9.14a(f), the NRC will respond to the request as provided in § 9.9. If the request is expected to require more than four hours of search time to locate the requested records and the NRC has not waived fees under § 9.14a(f), the NRC will notify the requester that fees will be assessed. The notification

[Note removed 49 FR19623]

[Note removed 49 FR 19623]

shall include the estimated cost of search fees and the nature of the search required. Requesters are encouraged to discuss with the NRC the possibility of narrowing the scope of the request while retaining the requester's original objective. The requester will be advised that he may agree to bear the estimated costs, submit a deposit equal to the estimated cost of complying with the request, or submit a request for waiver or reduction of fees pursuant to § 9.14a.

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(b) Within 10 working days of the receipt of NRC's notice that fees will be assessed, the requester shall notify NRC in writing that he agrees to bear the estimated costs, submit a deposit equal to the estimated cost of responding to the request or submit a request for waiver or reduction of fees pursuant to § 9.14a. In making a request for waiver or reduction of fees, a requester must provide the information required by § 9.14a(c).

(c) Within 10 working days after receipt of a request for the waiver or reduction of fees made in accordance with § 9.14a, the NRC will waive or reduce the fees and notify the requester of the NRC's intent to promptly provide the records or will deny the request and provide a statement to the requester as to why the request does not meet the requirements of § 9.14a(e).

45 FR 9729

(d) In those cases where a waiver of fees was requested and denied and the requester has agreed to bear the estimated cost, the requester may within 30 days of receipt of the requested documents resubmit a request for a waiver or reduction of fees if the receipt of documents has materially changed the information originally furnished by the requester pursuant to 9.14a(c).

44 FR 15998

(e) As provided in §§ 9.11 and 9.15, a denial of a request to waive or reduce fees may be appealed within 30 days to the Executive Director for Operations or to the Commission, as appropriate.

50 FR 27214

§ 9.15 Committees, boards, panels, and offices reporting to the Commission

(a) For boards, panels, and offices reporting directly to the Commission, and the Office of the Executive Legal Director, the initial determination on a request for records or request for waiver or reduction of fees for locating and reproducing such records, required by § 9.9 shall be made by the head of such board, panel, or office or his designee, instead of the Director, Office of Administration, and an appeal of an adverse determination shall be made to the Secretary of the Commission instead of the Executive Director for Operations.

(b) The Advisory Committee Management Officer shall make the initial determination required by § 9.9 on requests for records of advisory committees established pursuant to Part 7 of this chapter, including the Advisory Committee on Reactor Safeguards, or requests for waiver or reduction of fees for locating and reproducing such records, and an appeal of an adverse determination shall be to the Secretary of the Commmission.

44 FR 15998

(c) The head of boards, panels, and offices reporting directly to the Commission, and the Advisory Committee Management Officer for advisory committees established pursuant to Part 7 of this chapter, will make the initial determination required by paragraph (a) and (b) of this section only after consultation with the Office of the General Counsel.

§ 9.16 Annual Report to Congress.

(a) On or before March 1 of each calendar year, the Director, Office of Administration, will submit a report covering the preceding calendar year to the Speaker of the House of Representatives and President of the Senate for referral to the appropriate committees of the Congress. The report will include—

(1) the number of determinations made by the NRC not to comply with requests for records made to the NRC under this Part and the reasons for each such determination;

40 FR 7893

(2) the number of appeals made by persons under § 9.11, the results of such appeals, and the reason for the action upon each appeal that results in a denial of information;

(3) the names and titles or positions of each person responsible for the denial of records requested under this section, and the number of instances of participation for each:

(4) the results of each proceeding conducted pursuant to 5 U.S.C. 552(a)(4)(F), including a report of the disciplinary action taken against the officer or employee who was primarily responsible for improperly withholding records or an explanation of why disciplinary action was not taken;

(5) a copy of every rule made by the NRC regarding this Part;

(6) a copy of the fee schedule and the total amount of fees collected by the NRC for making records available under this Part; and

(7) such other information as indicates efforts to administer fully the provisions of 5 U.S.C. 552.

(b) A copy of each report to the Congress made pursuant to paragraph (a) of this section will be made available for public inspection and copying in the NRC Public Document Room.

40 FR 44483

Subpart B—Privacy Act Regulations

§ 9.50 Scope of subpart.

This subpart implements the provisions of section 3 of the Privacy Act of 1974, Pub. L. 93–579, 5 U.S.C. 552a, with respect to (a) the procedures by which individuals may determine the existence of, seek access to and request correction of NRC records concerning themselves, and (b) the requirements applicable to NRC personnel with respect to the use and dissemination of such records. The regulations in this subpart apply to all records which are retrievable from a system of records under the control of the Nuclear Regulatory Commission by the use of an individual's name or of an identifying number, symbol, or other identifying particular assigned to such individual. Except where specifically provided otherwise, this subpart applies to all NRC records maintained on individuals whether they predate or postdate September 27, 1975.

§ 9.51 Definitions.

As used in this subpart:

(a) "Individual" means a citizen of the United States or an alien lawfully admitted for permanent residence.

(b) The term "maintain" includes maintain, collect, use or disseminate.

(c) "Record' means any item, collection or grouping of information about an individual that is maintained by the NRC, including, but not limited to, his education, financial transactions, medical history, employment history or criminal history, and that contains the individual's name, or the identifying number, symbol or other identifying particular assigned to the individual, such as a finger or voice print or a photograph.

40 FR 44483

(d) "System manager" means the NRC official responsible for maintaining a system of records.

(e) "Systems of records" means a group of records under the control of the NRC from which information is retrieved by the name of an individual or by an identifying number, symbol, or other identifying particular assigned to an individual.

(f) "Statistical record" means a record in a system of records maintained for statistical research or reporting purposes only and not used in whole or in part in making any determination about an identifiable individual, except as provided by the Census Act, 13 U.S.C. 8.

(g) "Routine use" means, with respect to the disclosure of a record, the use of such record for a purpose which is compatible with the purpose for which it was collected, as described in a notice published in the FEDERAL REGISTER.

PROCEDURES APPLICABLE TO REQUESTS BY INDIVIDUALS FOR INFORMATION, ACCESS OR AMENDMENT OF RECORDS MAINTAINED ABOUT THEM

PRESENTATION OF REQUESTS

§ 9.52 Types of requests.

(a) Individuals may make the following requests respecting records about themselves maintained by NRC in a system of records subject to the provisions of the Privacy Act of 1974:

(1) Request a determination whether a record about the individual is contained in a system of records.

(2) Request access to a record about the individual. Access requests may include requests to review the record and to have a copy made of all or any portion thereof in a form comprehensible to the individual.

(3) Request correction or amendment of a record about the individual.

(b) *Requests for accounting of disclosures.* Individuals may, at any time, request an accounting by NRC of disclosures to any other person or Government agency of any record about themselves contained in a system of records controlled by NRC, except the following: (1) Disclosures made pursuant to the Freedom of Information Act, 5 U.S.C. 552; (2) disclosures made within the Nuclear Regulatory Commission; (3) disclosures made to another Government agency or instrumentality for an authorized law enforcement activity pursuant to 5 U.S.C. 552a(b)(7); (4) disclosures expressly exempted by NRC regulations from the requirements of 5 U.S.C. 552a(c)(3) pursuant to 5 U.S.C. 552a(k).

§ 9.53 Requests: how and where presented.

40 FR 444483

(a) Requests may be made in person or in writing. Assistance regarding requests or other matters relating to the Privacy Act of 1974 may be obtained by writing to the Director, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Requests relating to records in multiple systems of records should be made to the Director, Office of Administration, U.S. Nuclear Regulatory Commission, Washington; D.C. 20555. The Director, or his designee, shall assist the requestor in identifying his request more precisely and shall be responsible for forwarding the request to the appropriate system manager.

41 FR 20645

(b) All written requests shall be made to the Director, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and should clearly state on the envelope and in the letter, as appropriate: "Privacy Act Request," "Privacy Act Disclosure Accounting Request," "Privacy Act Correction Request." A request that is not so marked will be deemed not to have been received by the NRC until it is actually received by the Director, Office of Administration.

(c) Requests may be made in person during official hours at the U.S. Nuclear Regulatory Commission office where the record is located, as listed in the "Notice of System of Records" for the system in which the record is contained.

§ 9.54 Verification of identity of individuals making requests.

(a) Identification requirements in paragraphs (a) (1) and (2) of this section are applicable to any individual who makes requests respecting records about himself, except that no verification of identity shall be required if the records requested are available to the public under the provisions of the Freedom of Information Act. With respect to certain sensitive records, additional requirements for verification of identity stated in the appropriate published "Notice of System of Records" may be imposed.

(1) *Written requests*. An individual making a written request respecting a record about himself may establish his identity by a signature, address, date of birth, employee identification number if any, and one other item of identification such as a photocopy of a driver's license or other document.

40 FR 44483

(2) *Requests in person*. An individual making a request in person respecting a record about himself may establish his identity by the presentation of a single document bearing a photograph (such as a passport or identification badge) or by the presentation of two items of identification which do not bear a photograph but do bear a name, address and signature (such, as a driver's license or credit card).

(b) *Inability to provide requisite documentation of identity*. An individual making a request in person or in writing respecting a record about himself who cannot provide the necessary documentation of identity may provide a notarized statement, swearing or affirming to his identity and to the fact that he understands that penalties for false statements may be imposed pursuant to 18 U.S.C. 1001, and that penalties for obtaining a record concerning an individual under false pretenses may be imposed pursuant to 5 U.S.C. 552a(i)(3). Forms for such notarized statements may be obtained on request from the Director, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(c) *Verification of parentage or guardianship*. In addition to establishing the identity of the minor, or other individual he represents as required in paragraph (a) of this section, the parent or legal guardian of a minor or of an individual judicially determined to be incompetent shall establish his status as parent or guardian by furnishing a copy of a birth cerificate of the minor showing parentage or a copy of a court order establishing guardianship.

§ 9.55 Specification of records.

40 FR 44483

(a)(1) Requests relating to records shall, insofar as practicable, specify the nature of the record sought, the approximate dates covered by the record, the system of records in which the record is thought to be included and the system manager having custody of the record system as shown in the annual compilation, "Notices of Records Systems", published by the General Services Administration. Requests shall, in addition, comply with any additional specification requirements contained in the published "Notice of System of Records" for that system.

(2) Requests for correction or amendment of records shall, in addition, specify the particular record involved, state the nature of the correction or amendment sought and furnish justification for the correction or amendment.

(b) Requests which do not contain information sufficient to identify the record requested will be returned promptly to the requestor, with a notice indicating what information is lacking. Individuals making requests in person will be informed of any deficiency in the specification of records at the time the request is made. Individuals making requests in writing will be notified of any such deficiency when their request is acknowledged.

§ 9.56 Accompanying persons.

An individual requesting access to records about himself may be accompanied by another individual of his own choosing. Both the individual requesting access and the individual accompanying him shall sign the required form indicating that the Nuclear Regulatory Commission is authorized to discuss the contents of the subject record in the presence of both individuals.

NRC PROCEDURES FOR PROCESSING REQUESTS

§ 9.60 Acknowledgment of requests.

(a) Written requests by individuals to verify the existence of, obtain access to or correct or amend records about themselves maintained by NRC in a system of records subject to the provisions of the Privacy Act of 1974, shall be acknowledged in writing by the Director, Office of Administration, or his designee, within ten working days after date of actual receipt. The acknowledgment shall advise the requestor if any additional information is needed to process the request. Wherever practicable, the acknowledgment shall notify the individual whether his request to obtain access to the record or to correct or amend the record has been granted or denied.

(b) When an individual requests access to records or permission to correct or amend records in person, every effort will be made to make an immediate determination as to whether access or correction or amendment should be granted. If an immediate determination cannot be made, the request will be processed in the same manner as a written request. Records will be made available for immediate inspection whenever possible.

40 FR 44483

§ 9.61 Procedures for processing requests for records exempt in whole or in part.

(a) When an individual requests information concerning the existence of, or access to, records about himself which have been compiled in reasonable anticipation of a civil action or proceeding in either a court or before an administrative tribunal, the NRC shall advise the individual only that no record available to him pursuant to the Privacy Act of 1974 has been identified.

(b) *Specific exemptions pursuant to 5 U.S.C. 552a(k)*. Individual requests for access to records which have been exempted from access pursuant to the provisions of 5 U.S.C. 552a(k) and § 9.95 shall be processed as follows:

44 FR 50804

(1) *Information classified pursuant to Executive Order 12065 and exempted pursuant to 5 U.S.C. 552a(k)(1)*. Requested information classified by NRC will be reviewed by the responsible official of the NRC to determine whether it continues to warrant classification under the criteria of Section 1-301 of Executive Order 12065." Information which no longer warrants classification under these criteria shall be declassified and made available to the individual. If the requested information has been classified by another agency, the responsible official of the NRC will request the classifying agency to review the information to ascertain if classification is still warranted. If the information continues to warrant classification, the individual shall be advised that the information sought is classified, that it has been reviewed and continues to warrant classification, and that it has been exempted from access pursuant to 5 U.S.C. 552a(k)(1)

40 FR 44483

(2) *Investigatory material compiled for law enforcement purposes exempted pursuant to 5 U.S.C. 552a(k)(2)*. Requests shall be responded to in the manner provided in paragraph (a) of this section unless a review of the information indicates that the information has been used or is being used to deny the individual any right, privilege or benefit for which he is eligible or to which he would otherwise be entitled under Federal law. In that event, the individual shall be advised of the existence of the information and shall be provided the information except to the extent it would reveal the identity of a confidential source. Information that would reveal the identity of a confidential source shall be extracted or summarized in a manner which protects the source and the sum-

40 FR 44483

mary or extract shall be provided to the requesting individual.

(3) *Material within a system of records required by statute to be maintained and used solely as statistical records and exempted pursuant to 5 U.S.C. 552a(k)(4).* The exempted information requested will be reviewed by the responsible official of the NRC to determine whether it continues to warrant exemption. Information which no longer warrants exemption shall be made available to the individual. If the information continues to warrant exemption, the individual shall be advised that the information sought is exempt from disclosure, that it has been reviewed and continues to warrant exemption, and that it has been exempted from access pursuant to 5 U.S.C. 552a(k)(4).

(4) *Investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for Federal civilian employment, Federal contracts, or access to classified information and exempted pursuant to 5 U.S.C. 552a(k)(5).* Information exempted pursuant to 5 U.S.C. 552a(k)(5) shall be made available to an individual upon request except to the extent that the information would reveal the identity of a confidential source. Material that would reveal the identity of a confidential source shall be extracted or summarized in a manner which protects the source and the summary or extract shall be provided to the requesting individual.

(5) *Testing or examination material exempted pursuant to 5 U.S.C. 552a(k)(6).* Testing or examination material used solely to determine individual qualifications for appointment or promotion in the Federal service which has been exempted pursuant to 5 U.S.C. 552a(k)(6) shall not be made available to an individual if disclosure would compromise the objectivity or fairness of the testing or examination process but may be made available if no possibility of such compromise exists.

41 FR 44997.

§ 9.62 Special procedures.

(a) *Records under the control of another government agency.* (1) *Medical records.* Requests received by NRC pertaining to medical records under the control of the U.S. Public Health Service or another Government agency will either be referred to the appropriate agency or returned to the requestor with the name of the controlling Government agency, if known, within ten working days after receipt by NRC. NRC will inform the requestor of any referral of his request to another Government agency at the time the referral is made.

40 FR 44483

(2) *Nonmedical records.* Requests received by NRC pertaining to nonmedical records under the control of another Government agency will be returned to the requestor with the name of the controlling Government agency, if known, within ten working days after receipt by NRC.

DETERMINATION AND APPEALS

§ 9.65 Access determinations; appeals.

(a) *Initial determinations.* The Director, Office of Administration, or his designee, with the advice of the system manager having control of the record to which access is requested, shall determine whether access to the record is available under the Privacy Act and notify the requesting individual in person or in writing of that determination. Unless the request presents unusual difficulties or involves extensive numbers of records, individuals shall be notified of determinations to grant or deny access within 30 working days after receipt of the request.

(1) Notices granting access shall inform the individual when and where the requested record may be seen, how copies may be obtained, and of any fees or anticipated charges which may be incurred pursuant to § 9.85 of this subpart.

(2) Notices denying access shall state the reasons for the denial, and advise the individual that he may appeal the denial to the Executive Director for Operations in accordance with the procedures set forth in this section.

41 FR 20645

(b) *Appeals from denials of access.* If an individual has been denied access to a record the individual may request a final review and determination of his request by the Executive Director for Operations. A request for final review of an initial determination should be filed within 60 days of the receipt of the initial determination, shall be in writing, shall be addressed to the Executive Director for Operations, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and should be clearly marked on the envelope and in the letter "Privacy Act Appeal—Denial of Access." A request that is not so marked will be deemed not to have been received by the NRC until it is actually received by the Executive Director for Operations.

40 FR 44483

(c) *Final determinations.* (1) The Executive Director for Operations, or his designee, shall make a final determination within 30 working days of receipt of the request for final review, unless he extends the time for good cause shown such as the need to obtain additional information, the volume of records involved or the complexity of the issue. The extension of time shall not exceed 30 additional working days. The requestor shall be advised in advance of any extension of time and of the reasons therefor.

(2) If the Executive Director for Operations, or his designee, determines that access was properly denied because the information requested has been exempted from disclosure, he shall undertake a review of the exemption to determine whether the information should continue to be exempt from disclosure. The Executive Director for Operations, or his designee, shall notify the individual in writing of his final determination to grant or deny the request for access. Notices denying access shall state the reasons therefor and shall advise the individual of his right to judicial review pursuant to 5 U.S.C. 552a(g).

§ 9.66 Determinations authorizing or denying correction of records; appeals.

(a) *Initial determinations.* (1) The Director, Office of Administration, or his designee, with the advice of the system manager having control of the record, shall determine whether to authorize or refuse correction or amendment of a record. Unless the request presents unusual difficulties or involves extensive numbers of records, individuals shall be notified of determinations to authorize or refuse correction or amendment of a record within 30 working days after receipt of the request. In making this determination, the Director, or his designee, shall be guided by the following standards:

(i) Records shall contain only such information about an individual as is relevant and necessary to accomplish an NRC function required to be accomplished by statute or by executive order of the President;

(ii) Records used by NRC in making any determination about any individual shall be as accurate, relevant, current, and complete as is reasonably necessary to assure fairness to the individual in the determination;

(iii) No record shall describe how any individual has exercised rights guaranteed by the First Amendment unless such record is expressly authorized by statute or by the individual about whom the record is maintained, or is pertinent to and within the scope of an authorized law enforcement activity.

(2) If correction or amendment of a record is authorized, the Director, Office of Administration, or his designee, shall correct or amend the record, notify the requesting individual in writing that the correction or amendment has been made and provide the individual with a courtesy copy of the corrected record.

(3) If correction or amendment of a record is refused, the Director, Office of Administration, or his designee, shall notify the requesting individual in writing of the refusal and the reasons therefor, and shall advise the individual of his right to request a review of the refusal by the Executive Director for Operations in accordance with the procedures set forth in this section.

41 FR 20645

(b) *Appeals from initial adverse determinations.* If an individual's request to amend or correct a record has been denied, in whole or in part, the individual may request a final review and determination of his request by the Executive Director for Operations. A request for final review of an initial determination should be filed within 60 days of the receipt of the initial determination, shall be in writing, shall be addressed to the Executive Director for Operations, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and should be clearly marked on the envelope and in the letter "Privacy Act Correction Appeal." An appeal that is not so marked will be deemed not to have been received by the NRC until it is actually received by the Executive Director for Operations. Requests for final review shall set forth the specific item of information sought to be corrected or amended and should include, where appropriate, documents supporting the correction or amendment.

40 FR 44483

(c) *Final determinations.* (1) The Executive Director for Operations, or his designee, shall make a final determination within 30 working days of receipt of the request for final review unless, for good cause shown such as the need to obtain additional information, the volume of records involved or the complexity of the issue, he extends the time for making the final determination. The extension of time shall not exceed 30 addi-

40 FR 44483

tional working days. The requestor shall be advised in advance of any extension of time and the reasons therefor.

(2) If the Executive Director for Operations, or his designee, makes a final determination that an amendment or correction of the record is warranted on the facts, he shall notify the Director, Office of Administration, to correct or amend the record pursuant to the procedures in § 9.66(a)(2).

(3) If the Executive Director for Operations, or his designee, makes a final determination that an amendment or correction of the record is not warranted on the facts, he shall notify the individual in writing of his refusal to authorize correction or amendment of the record in whole or in part, and of the reasons therefor, and shall advise the individual of his right to provide a "Statement of Disagreement" for the record and of his right to judicial review pursuant to 5 U.S.C. 552a(g).

§ 9.67 Statements of disagreement.

41 FR 20645

(a) Written "Statements of Disagreement" may be furnished by the individual within 30 working days of the date of receipt of the final adverse determination of the Executive Director for Operations. "Statements of Disagreement" shall be addressed to the Executive Director for Operations, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and should be clearly marked on the statement and on the envelope "Privacy Act Statement of Disagreement".

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(b) The Executive Director for Operations, or his designee, shall be responsible for ensuring that: (1) The "Statement of Disagreement" is included in the system or systems of records in which the disputed item of information is maintained, and (2) the original record is marked to indicate the information disputed, the existence of a "Statement of Disagreement", and the location of the "Statement of Disagreement" within the system of records.

§ 9.68 NRC Statements of Explanation.

The Executive Director for Operations, or his designee, may, if he deems it appropriate, prepare a concise statement of the reasons why the requested amendments or corrections were not made. Any NRC "Statement of Explanation" shall be included in the system of records in the same manner as the "Statement of Disagreement". Courtesy copies of the NRC statement and of the notation of dispute as marked on the original record shall be furnished to the individual who requested correction or amendment of the record.

§ 9.69 Notices of correction or dispute.

(a) When a record has been corrected upon request or when a "Statement of Disagreement" has been filed, the Director, Office of Administration, or his designee, shall, within 30 working days thereof, advise all prior recipients of the affected record whose identity can be determined pursuant to an accounting of disclosures required by the Privacy Act or any other accounting previously made, of the correction or of the filing of the "Statement of Disagreement".

(b) Any disclosure of disputed information occurring after a "Statement of Disagreement" has been filed shall clearly identify the specific information disputed and be accompanied by a copy of the "Statement of Disagreement" and a copy of any NRC "Statement of Explanation".

DISCLOSURE TO OTHERS OF RECORDS ABOUT INDIVIDUALS

§ 9.80 Disclosure of record to persons other than the individual to whom it pertains.

(a) NRC Commissioners and NRC personnel shall not disclose any record which is contained in a system of records maintained by NRC by any means of communication to any person, or to another Government agency, except pursuant to a written request by, or with the prior written consent of, the individual to whom the record pertains, unless disclosure of the record is:

(1) To NRC Commissioners and NRC personnel who have a need for the record in the performance of their duties;

(2) Required under 5 U.S.C. 552;

(3) For a routine use published in the FEDERAL REGISTER;

(4) To the Bureau of the Census for purposes of planning or carrying out a census or survey or related activity pursuant to the provisions of Title 13 of the United States Code;

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(5) To a recipient who has provided the agency with advance adequate written assurance that the record will be used solely as a satistical research or reporting record and the record is transferred in a form that is not individually identifiable. The advance written statement of assurance shall (i) state the purpose for which the record is requested, and (ii) certify that the record will be used only for statistical purposes. Prior to release for statistical purposes in accordance with the provisions of this paragraph, the record shall be stripped of all personally identifying information and reviewed to ensure that the identity of any individual cannot reasonably be determined by combining two or more statistical records;

(6) To the National Archives of the United States as a record which has sufficient historical or other value to warrant its continued preservation by the United States Government, or to the Administrator of General Services or his designee for evaluation to determine whether the record has such value;

(7) To another agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States for a civil or criminal law enforcement activity if the activity is authorized by law, and if the head of the agency or instrumentality has made a written request to the NRC specifying the particular portion of the record desired and the law enforcement activity for which the record is sought. A record may be disclosed to a law enforcement agency at the initiative of the NRC if criminal conduct is suspected, provided that such disclosure has been established as a routine use by publication in the FEDERAL REGISTER, and the instance of misconduct is directly related to the purpose for which the record is maintained;

(8) To any person upon a showing of compelling circumstances affecting the health or safety of any individual;

(9) To either House of Congress or, to the extent of matter within its jurisdiction, to any committee or subcommittee thereof or to any joint committee of the Congress or to any subcommittee of such joint committee;

(10) To the Comptroller General, or any of his authorized representatives, in the course of the performance of the duties of the General Accounting Office; or

(11) Pursuant to the order of a court of competent jurisdiction.

§ 9.81 Notices of subpoenas.

When records concerning an individual are subpoenaed or otherwise disclosed pursuant to court order, the NRC officer or employee served with the subpoena shall be responsible for assuring that the individual is notified of the disclosure within five days after such subpoena or other order becomes a matter of public record. The notice shall be mailed to the last known address of the individual and shall contain the following information: (1) The date the subpoena is returnable; (2) the court in which it is returnable; (3) the name and number of the case or proceeding; and (4) the nature of the information sought.

40 FR 44483

§ 9.82 Notices of emergency disclosures.

When information concerning an individual has been disclosed to any person under compelling circumstances affecting health or safety, the NRC officer or employee who made or authorized the disclosure shall notify the individual at his last known address within five days of the disclosure. The notice shall contain the following information: (a) The nature of the information disclosed; (b) the person or agency to whom the information was disclosed; (c) the date of the disclosure; and (d) the compelling circumstances justifying the disclosure.

FEES

§ 9.85 Fees.

(a) *When charged.* Fees shall not be charged for search for or review of records requested pursuant to this subpart or for making copies or extracts of records in order to grant access to records and make them available for review. Fees established pursuant to 31 U.S.C. 483a and 5 U.S.C. 552a(f)(5) shall be charged according to the schedule contained in paragraph (b) of this section for actual copies of records requested by individuals pursuant to the Privacy Act of 1974, unless the Director, Office of Administration, or his designee, waives the fee because of the inability of the individual to pay. Fees shall not be charged where they would amount, in the aggregate, to less than $3.

(b) *Schedule of fees.* Fees may only be assessed for reproduction charges for actual copies of records requested by individuals pursuant to the Privacy Act of 1974 in accordance with the following schedule:

(1) Record sizes up to 8½ x 14 inches made on office copying machines—$0.10 per page copy.

(2) Record sizes greater than 8½ x 14 inches—$0.10 for each 8½ x 14 inch unit or fraction thereof per page copy.

(3) Microfiche—8½ x 11 inches—$0.15 per page copy.

(4) The charge for reproducing records other than those specified above will be computed on the basis of NRC's direct costs.

(c) *Notice of anticipated charges.* When it is anticipated that fees chargeable under this section will amount to more than $3, and the requestor has not indicated in advance his willingness to pay fees as high as are anticipated, the requestor shall be notified of the amount of the anticipated cost before copies are made. The notification shall offer the requestor the opportunity to confer with NRC personnel with the object of reformulating the request to meet the requestor's needs at lower cost.

(d) *Form and place of payment.* Fee payments shall be by check, draft or money order payable to the U.S. Nuclear Regulatory Commission. No employee of NRC is authorized to accept payment of fees in cash.

(e) *Advance deposit.* Where the anticipated fee chargeable under this section exceeds $25, an advance deposit of 25% of the anticipated fee or $25, whichever is greater, may be required. Where a requestor has previously failed to pay a fee under this section, an advance deposit of the full amount of the anticipated fee may be required.

40 FR 44483

ENFORCEMENT

§ 9.90 Violations.

(a) An injunction or other court order may be obtained pursuant to 5 U.S.C. 552a(g)(1–3) to compel NRC to permit an individual to review, amend or copy a record pertaining to him, or to be accompanied by someone of his own choosing when he reviews his record. A court order may be obtained for the payment of a civil penalty imposed pursuant to 5 U.S.C. 552a(g)(4) if NRC intentionally or willfully fails to maintain a record accurately, or fails to comply with any provision of 5 U.S.C. 552a, or any provision of this subpart, if such failure results in an adverse determination or has an adverse effect on an individual. Court costs and attorney's fees may be awarded in civil actions.

(b) Any officer or employee of NRC who willfully maintains a system of records without meeting the notice requirements of 5 U.S.C. 552a(e)(4), or who willfully discloses information knowing such disclosure to be prohibited by 5 U.S.C. 552a or by any rules or regulations issued thereunder, may be guilty of a criminal misdemeanor and upon conviction may be fined up to $5000. Any person who knowingly and willfully requests or obtains any record concerning an individual from NRC under false pretenses may be convicted of a criminal misdemeanor and upon conviction may be fined up to $5000.

§ 9.95 Specific exemptions.

The following records, contained in the designated NRC Systems of Records (NRC–1, NRC–5, NRC–6, NRC–9, NRC–11, NRC–18, NRC–22, NRC–23, NRC–28, NRC–29, NRC–31, NRC–33, NRC–37, NRC–39, and NRC–40) are exempt from 5 U.S.C. a(c)(e); (d); (e)(i); (e)(4)(G), (H), (I), and (f) in accordance with 5 U.S.C. 552a(k). Each of these records is subject to the provisions of § 9.61 of this part:

(a) Appointment and Promotion Certification Records, NRC–1.

(b) Contracts Records Files, NRC–5.

(c) Development and Advancement for Regulatory Employees (DARE) Records, NRC–6.

(d) Equal Employment Opportunity Records Files, NRC–9.

(e) General Personnel Records (Official Personnel Folder and Related Records), NRC–11.

(f) Office of Inspector and Auditor Index File and Associated Records, NRC–18.

(g) Personnel Performance Appraisals, NRC–22.

(h) Personnel Research and Test Validation Records, NRC–23.

(i) Recruiting, Examining and Placement Records, NRC–28.

(j) Document Control System, NRC–29.

(k) Correspondence and Records Branch, Office of the Secretary, NRC–31.

(l) Special Inquiry File, NRC–33.

(m) Information Security Files and Associated Records, NRC–37

(n) Personnel Security Files and Associated Records, NRC–39.

(o) Facility Security Support Files and Associated Records, NRC–40

47 FR 4676

Subpart C—Government in the Sunshine Act Regulations

§ 9.100 Scope of Subpart.

This subpart prescribes procedures pursuant to which NRC meetings shall be open to public observation pursuant to the provisions of 5 U.S.C. Sec. 552b. This subpart does not affect the procedures pursuant to which NRC records are made available to the public for inspection and copying which remain governed by subpart A, except that the exemptions set forth in § 9.104(a) shall gover in the case of any request made pursuant to § 9.8 to copy or inspect the transcripts, recordings or minutes described in § 9.108. Access to documents considered at NRC meetings shall continue to be governed by Subpart A of this Part.

§ 9.101 Definitions.

As used in this subpart:

(a) "Commission" means the collegial body of five Commissioners or a quorum thereof as provided by section 201 of the Energy Reorganization Act of 1974, or any subdivision of that collegial body authorized to act on its behalf, and shall not mean any body not composed of members of that collegial body.

(b) "Commissioner" means an individual who is a member of the Commission.

42 FR 12875

(c) "Meeting" means the deliberations of at least a quorum of Commissioners where such deliberations determine or result in the joint conduct or disposition of official Commission business, that is, where discussions are sufficiently focused on discrete proposals or issues as to cause or to be likely to cause the individual participating members to form reasonably firm positions regarding matters pending or likely to arise before the agency. Deliberations required or permitted by § 9.105, 9.108, or 9.108(c) do not constitute "meetings" within this definition.

50 FR 20889

(d) "Closed meeting" means a meeting of the Commission closed to public observation as provided by § 9.104.

(e) "Open meeting" means a meeting of the Commission open to public observation pursuant to this subpart.

(f) "Secretary" means the Secretary to the Commission.

(g) "General Counsel" means the General Counsel of the Commission as provided by section 25(b) of the Atomic Energy Act of 1954 and section 201(f) of the Energy Reorganization Act of 1974, and, until such time as the offices of that officer are in the same location as those of the Commission, any member of his office specially designated in writing by him pursuant to this subsection to carry out his responsibilities under this subpart.

§ 9.102 General requirement.

Commissioners shall not jointly conduct or dispose of Commission business in Commission meetings other than in accordance with this subpart. Except as provided in § 9.104, every portion of every meeting of the Commission shall be open to public observation.

§ 9.103 General provisions.

The Secretary shall ensure that all open Commission meetings are held in a location such that there is reasonable space, and adequate visibility and acoustics, for public observation. No additional right to participate in Commission meetings is granted to any person by this subpart. An open meeting is not part of the formal or informal record of decision of the matters discussed therein except as otherwise required by law. Statements of views or expressions of opinion made by Commissioners or NRC employees at open meetings are not intended to represent final determinations or beliefs.

42 FR 12875

Such statements may not be pleaded, cited, or relied upon before the Commission or in any proceeding under Part 2 of these regulations (10 CFR Part 2) except as the Commission may direct.

43 FR 37420

Members of the public attending open Commission meetings may use small electronic sound recorders to record the meeting, but the use of other electronic recording equipment and cameras requires the advance written approval of the Secretary. 43 FR 13065

§ 9.104 Closed meetings.

(a) Except where the Commission finds that the public interest requires otherwise, Commission meetings shall be closed, and the requirements of §§ 9.105 and 9.107 shall not apply to any information pertaining to such meeting otherwise required by this subpart to be disclosed to the public, where the Commission determines in accordance with the procedures of § 9.105 that opening such meetings or portions thereof or disclosing such information, is likely to:

(1) Disclose matters that are (i) specifically authorized under criteria established by an Executive order to be kept secret in the interests of national defense or foreign policy, and (ii) in fact properly classified pursuant to such Executive order;

(2) Relate solely to the internal personnel rules and practices of the Commission;

(3) Disclose matters specifically exempted from disclosure by statute (other than 5 U.S.C. 552) provided that such statute (i) requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue, or (ii) establishes particular criteria for withholding or refers to particular types of matters to be withheld; 42 FR 12875

(4) Disclose trade secrets and commercial or financial information obtained from a person and privileged or confidential, including such information as defined in § 2.790(d) of this title;

(5) Involve accusing any person of a crime, imposing a civil penalty on any person pursuant to 42 U.S.C. 2282 or 42 U.S.C. 5846, or any revocation of any license pursuant to 42 U.S.C. Sec. 2236, or formally censuring any person;

(6) Disclose information of a personal nature where such disclosure would constitute a clearly unwarranted invasion of personal privacy;

(7) Disclose investigatory reports compiled for law enforcement purposes, including specifically enforcement of the Atomic Energy Act of 11954, as amended, 42 U.S.C. 2011 et seq., and the Energy Reorganization Act of 1974, as amended, 42 U.S.C. 5801 et seq., or information which if written would be contained in such records, but only to the extent that the production of such records or information would: (i) Interfere with enforcement proceedings, (ii) deprive a person of a right to a fair trial or an impartial adjudication, (iii) constitute an unwarranted invasion of personal privacy, (iv) disclose the identity of a confidential source and, in the case of a record compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, confidential information furnished only by the confidential source, (v) disclose investigative techniques and procedures, or (vi) endanger the life or physical safety of law enforcement personnel;

(8) [Reserved]

(9) Disclose information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed Commission action, except that this subparagraph shall not apply in any instance where the Commission has already disclosed to the public the content or nature of its proposed action, or where the Commission is required to make such disclosure on its own initative prior to taking final action on such proposal; or

(10) Specifically concern the Commission's issuance of a subpoena, or the Commission's participation in a civil action or proceeding or an action or proceeding before a state or federal administrative agency, an action in a foreign court or international tribunal, or an arbitration, or the initiation, conduct or disposition by the Commission of a particular case of formal agency adjudication pursuant to 5 U.S.C. 554 or otherwise involving a determination on the record after an opportunity for a hearing pursuant to Part 2 or similar provisions. 42 FR 12875

(b) Examples of situations in which Commission action may be deemed to be significantly frustrated are: (1) If opening any Commission meeting or negotiations would be likely to disclose information provided or requests made to the Commission in confidence by persons outside the Commission and which would not have been provided or made otherwise; (2) if opening a meeting or disclosing any information would reveal legal or other policy advice, public knowledge of which could substantially affect the outcome or conduct of pending or reasonably anticipated litigation or negotiations; or (3) if opening any meeting or disclosing any information would reveal information requested by or testimony or proposals to be given to other agencies of government, including the Congress and the Executive Branch before the requesting agency would receive the information, testimony or proposals. The examples in the above sentence are for illustrative purposes only and are not intended to be exhaustive.

§ 9.105 Commission procedures.

(a) Action under § 9.104 shall be taken only when a majority of the entire membership of the Commission votes to take such action. A separate vote of the Commissioners shall be taken with respect to each Commission meeting a portion or portions of which are proposed to be closed to the public pursuant to § 9.104, or which respect to any information which is proposed to be withheld under § 9.105(c). A single vote may be taken with respect to a series of meetings, a portion or portions of which are proposed to be closed to the public, or with respect to any information concerning such series of meetings, so long as each meeting in such series involves the same particular matters and is scheduled to be held no more than thirty days after the initial meeting in such series. The vote of each Commissioner participating in such vote shall be recorded and no proxies shall be allowed.

(b) Within one day of any vote taken pursuant to paragraph (a) of this section, § 9.106(a) or § 9.108(c) the Secretary shall make publicly available in the Public Document Room a written copy of such vote reflecting the vote of each member on the question. If a portion of a meeting is to be closed to the public, the Secretary shall, within one day of the vote taken pursuant to paragraph (a) of this section or § 9.106(a), make publicly available in the Public Document Room a full written explanation of its action closing the portion together with a list of all persons expected to attend the meeting and their affiliation. 42 FR 12875

(c) The notices and lists required by paragraph (b) of this section to be made public may be withheld from the public to the extent that the Commission determines that such information itself would be protected against disclosure by § 9.104(a). Any such determination shall be made independently of the Commission's determination pursuant to paragraph (a) of this section to close a meeting, but in accordance with the procedure of that subsection. Any such determination, including a written explanation for the action and the specific provision or provisions of § 9.104(a) relied upon, must be made publicly available to the extent permitted by the circumstances.

§ 9.106 Persons affected and motions for reconsideration.

(a) Whenever any person whose interests may be directly affected by a portion of a meeting requests that the Commission close such portion to the public for any of the reasons referred to in paragraphs (a) (5), (6), or (7) of § 9.104, the Commission, upon request of any one Commissioner, shall vote by recorded vote whether to close such meeting.

PART 9 • PUBLIC RECORDS

(b) Any person may petition the Commission to reconsider its action under § 9.105(a) or paragraph (a) of this section by filing a petition for reconsideration with the Commission within seven days after the date of such action and before the meeting in question is held.

(c) A petition for reconsideration filed pursuant to paragraph (b) of this section shall state specifically the grounds on which the Commission action is claimed to be erroneous, and shall set forth, if appropriate, the public interest in the closing or opening of the meeting. The filing of such a petition shall not act to stay the effectiveness of the Commission action or to postpone or delay the meeting in question unless the Commission orders otherwise.

§ 9.107 Public announcement of Commission meetings.

(a) In the case of each meeting, the Secretary shall make public announcement, at least one week before the meeting, of the time, place, and subject matter of the meeting, whether it is to be open or closed to the public, and the name and phone number of the official designated by the Commission to respond to requests for information about the meeting. Such announcement shall be made unless a majority of the members of the Commission determines by a recorded vote that Commission business requires that such meeting be called at an earlier date, in which case the Secretary shall make public announcement of the time, place and subject matter of such meeting, and whether open or closed to the public, at the earliest practical time.

(b) The time or place of a meeting may be changed following the public announcement required by paragraph (a) of this section only if the Secretary publicly announces such changes at the earliest practicable time. The subject matter of as meeting, or the determination of the Commission to open or close a meeting, or portion of a meeting, to the public, may be changed following the public announcement required by this subsection only if: (1) A majority of the entire membership of the Commission determines by a recorded vote that Commission business so requires and that no earlier announcement of the change was possible, and (2) the Secretary publicly announces such change and the vote of each member upon such change at the earliest practicable time.

42 FR 62471

(c) Immediately following each public announcement required by this section, notice of the time, place, and subject matter of a meeting, whether the meeting is open or closed, any change in one of the preceding, and the name and phone number of the official designated by the Commission to respond to requests for information about the meeting, shall also be submitted for publication in the FEDERAL REGISTER.

(d) The public announcement required by paragraph (a) of this section shall consist of the Secretary:

(1) Publicly posting a copy of the document in the Public Document Room at 1717 H Street, N.W., Washington, D.C.; and, to the extent appropriate under the circumstances;

(2) Mailing a copy to all persons whose names are on a mailing list maintained for this purpose;

(3) Submitting a copy for possible publication to at least two newspapers of general circulation in the Washington, D.C. metropolitan area;

42 FR 62471

(4) Any other means which the Secretary believes will serve to further inform any persons who might be interested.

(e) Action under the second sentence of paragraph (a) or (b) of this section shall be taken only when the Commission finds that the public interest in prompt Commission action or the need to protect the common defense or security or to protect the public health or safety overrides the public interest in having full prior notice of Commission meetings.

§ 9.108 Certification, transcripts, recordings and minutes.

(a) For every meeting closed pursuant to paragraphs (a) (1) through (10) of § 9.104 and for every determination pursuant to § 9.105(c), the General Counsel shall publicly certify at the time of the public announcement of the meeting, or if there is no public announcement at the earliest practical time, that, in his or her opinion, the meeting may be closed to the public, and shall state each relevant exemptive provision unless the Commission votes pursuant to § 9.105(c) that such certification is protected against disclosure by § 9.104(a). A copy of such certification, together with a statement from the presiding officer of the meeting setting forth the time and place of the meeting, and the persons present, shall be retained by the Commission. The Commission shall maintain a complete transcript or electronic recording adequate to record fully the proceedings of each meeting, or portion of a meeting closed to the public, except that in the case of a meeting, or portion of a meeting, closed to the public pursuant to paragraph (c)(10) of § 9.104, the Commission shall maintain such a transcript, or recording or a set of minutes. Such minutes shall fully and clearly describe all matters discussed and shall provide a full and accurate summary of any actions taken, and the reasons therefor, including a description of each of the views expressed on any item and the record of any rollcall vote (reflecting the vote of each Commissioner on the question). All documents considered in connection with any action shall be identified in such minutes.

42 FR 12875

(b) The Commission shall make promptly available to the public, in the Public Document Room, the transcript, electronic recording, or minutes (as required by paragraph (a) of this section) of the discussion of any item on the agenda, or of any item of the testimony of any witness received at the meeting, except for such item or items of such discussion or testimony as the Commission determines pursuant to paragraph (c) of this section to contain information which may be withheld under § 9.104 or § 9.105(c). Copies of such transcript, or minutes, or a transcription of such recording disclosing the identity of each speaker, shall be furnished to any person upon payment of the actual cost of duplication or transcription as provided in § 9.14. The Secretary shall maintain a complete verbatim copy of the transcript, a complete copy of the minutes, or a complete electronic recording of each meeting, or portion of a meeting, closed to the public, for a period of at least two years after such meeting, or until one year after the conclusion of any Commission proceeding with respect to which the meeting or portion was held, whichever occurs later.

42 FR 12875

(c) In the case of any meeting closed pursuant to § 9.104, the Secretary of the Commission, upon the advice of the General Counsel and after consultation with the Commission, shall determine which, if any, portions of the electronic recording, transcript or minutes and which, if any, items of information withheld pursuant to § 9.105(c) contain information which should be withheld pursuant to § 9.104, in the event that a request for the recording, transcript, or minutes is received within the period during which the recording, transcript, or minutes must be retained, under subsection (b) of this section.

50 FR 20889

(d) If at some later time the Commission determines that there is no further justification for withholding any transcript, recording or other item of information from the public which has previously been withheld, then such information shall be made available.

42 FR 12875

§ 9.109 Report to Congress.

The Secretary shall annually report to the Congress regarding the Commission's compliance with the Government in the Sunshine Act, including a tabulation of the total number of open meetings, the total number of closed meetings, the reasons for closing such meetings and a description of any litigation brought against the Commission pursuant to the Government in the Sunshine Act, including any cost assessed against the Commission in such litigation (whether or not paid by the Commission). 42 FR 12875

Appendix A—Request for Declassification Review

The following guidance is provided for members of the public desiring a classification review of a document of the Nuclear Regulatory Commission pursuant to section 3.4 of Executive Order 12356 (47 FR 14874, April 6, 1982) and sections 2001.32 and 2001.34 of the Information Security Oversight Office Directive No. 1 covering the original and derivative classification, downgrading, declassification, and safeguarding of National Security Information (47 FR 27836, June 25, 1982). A Freedom of Information Act or Privacy Act request for a classified document may also be made in accordance with the procedures set forth in §§ 9.8 and 9.53 through 9.55 of this part.

47 FR 56314

1. Request for Declassification Review of Documents. a. Any person desiring a declassification review of an NRC document containing information classified as National Security Information by reason of the provisions of Execuive Order 12356 (or any predecessor Executive Order) should address such requests to the Director, Division of Security, U.S. Nuclear Regulatory Commission, Washington, DC, 20555.

b. Requests need not be made on any special form but shall, as specified in the Executive Order, reasonably describe the document to enable NRC personnel to identify and obtain the document from NRC records without expending more than a reasonable amount of effort.

c. Charges for locating and reproducing copies of records will be made in accordance with § 9.14 of this part.

2. Action on Requests for Declassification Review. a. Every effort will be made to complete action on each request within thirty (30) days of receipt of the request. If action cannot be completed within thirty (30) days, the requester shall be so advised by the Director, Division of Security, along with the reasons for the need for additional time. If the requester does not receive a decision on the request within sixty (60) days from the date of receipt of the request by NRC, the requester may appeal to the Chairman of the NRC Classification Review Committee for a decision on the request.

b. In the event the Director, Division of Security, determines that requested information must remain classified by reason of the provisions of Executive Order 12356, the requester shall be given prompt notification of that decision and shall be provided with a statement as to why the information or material cannot be declassified. Classified sections of the document will be identified, and the requester will be advised that a "sanitized" document can be provided with an appropriate unclassified description of the deleted information. Unclassified portions of the document will be made available to the requester unless withholding is warranted for some other reason under the provision of applicable law. If information is denied, the requester will be advised that the decision may be appealed to the NRC Classification Review Committee. An appeal should be made in writing addressed to the Chairman, Classification Review Committee, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Any such appeal should include a statement as to why the requester disagrees with the decision which is being appealed. 47 FR 56314

c. The NRC Classification Review Committee will normally render a decision within 30 days of the receipt of an appeal. If a longer period is likely to be required because of the need for consultations with other agencies or the requester, the requester will be advised of the time needed to complete review of the matter.

d. In the event the Director, Division of Security, or the Classification Review Committee, determines that the record is unclassified but the information appears to be of the type exempt from public disclosure under § 9.5 of this part, the requester shall be so notified in writing as provided in § 9.10 of this part.

3. Suggestions and complaints. Any person may make suggestions or complaints with respect to NRC's administration of the provisions of Executive Order 12356 and the ISOO Directive by writing to the Chairman, Classification Review Committee, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

4. Other Material. NRC Manual Chapters covering the NRC's classification and declassification policies and procedures are available for inspection and copying in the NRC's Public Document Room, 1717 H Street, NW., Washington, DC.

5. Classification Advice in General. These procedures are intended to supplement the policies and practices of the NRC to provide classification guidance with respect to information originated by persons working in the nuclear energy field. The NRC will respond as promptly as available resources permit to questions about the proper classification of information and material.

PART 9

PUBLIC RECORDS

PROPOSED RULE MAKING

49 FR 28072
Published 7/10/84

10 CFR Part 9

Production or Disclosure in Response to Subpoenas or Demands of Courts or Other Authorities

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) proposes to add Subpart D to Part 9 of Chapter 10 of the Code of Federal Regulations to prescribe procedures with respect to the production of documents or disclosure with respect to the production of documents or disclosure of information in response to subpoenas or demands of courts or other judicial or quasi-judicial authorities in state and Federal proceedings. The proposed rule would clarify the procedures to be followed by Commission employees in responding to demands for testimony, information or documents and would ensure that the responsibility for determining the response to the demands is placed on the appropriate Commission official.

DATE: Comment period expires August 9, 1984. Comments received after this date will be considered if practicable to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

ADDRESSES: Mail written comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

Deliver comments to: Room 1121, 1717 H Street, NW., Washington, DC between 8:15 a.m. and 5:00 p.m. weekdays. Examine comments received at: The NRC Public Document Room, 1717 H Street, NW., Washington, DC

FOR FURTHER INFORMATION CONTACT: Richard L. Black, Office of General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (202) 634–1493.

SUPPLEMENTARY INFORMATION: The Nuclear Regulatory Commission's inspection and investigation functions resulting in enforcement actions against NRC licensees have increased substantially over the past several years. As a result of this activity and in the wake of many cancellations of nuclear power plants, there are now increasing demands for access to NRC records and for testimony by NRC employees by parties in litigation to which the NRC is not a party. NRC personnel have been and are expected to be subpoenaed for depositions or testimony in those private actions and called upon to produce NRC records or to disclose information relating to licensing and enforcement activities. The NRC currently has no uniform written policy for dealing with these demands. It is the purpose of the proposed amendments to prescribe a uniform policy to provide NRC personnel with clear guidance on how to respond to subpoenas or other demands for disclosure. These amendments do not apply to those administrative actions conducted pursuant to NRC rules. They are limited to those activities which involve NRC licensing, regulatory, or enforcement activities. In addition these amendments do not provide any new or additional authority to withhold information or testimony.

Following the lead of other federal agencies that have established a "clearinghouse" or centralized decisionmaking approach to subpoenas, the proposed amendments establish that all subpoenas served on NRC personnel be referred to the General Counsel. The General Counsel is to review the proposed discovery, ascertain the scope of the proposal, and decide on the approach to be followed in each case, including authorizing litigation if necessary to resolve disputes between the NRC and the party seeking the discovery. In addition, the proposed amendments set forth the procedures to be followed in the event a response to a subpoena is required before instructions from the General Counsel are received.

In deciding whether and to what extent to make documents or testimony available pursuant to a demand, the General Counsel is to consider, among other things, whether the discovery would be proper under the general provisions governing discovery set forth in Fed. R. Civ. P. 26(c), and under the rules of procedure governing the case or matter in which the demand arose. The General Counsel must also consider whether disclosure is appropriate under the relevant substantive law concerning privilege; general statutes and regulations governing possession and use of government or corporate information; policy governing ongoing investigations or concerning investigative methods, and informants, and similar considerations. The General Counsel will advise the party seeking discovery of the results of the NCR's deliberations in writing as far in advance of the response date as is practicable. Commissioner Asselstine adds:

> I would particularly appreciate comments on whether the proposed rule should apply to former as well as current NRC employees.

Paperwork Reduction Act Statement

This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). This rule has been submitted to the Office of "Management and Budget for review and approval of the paperwork requirements.

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission hereby certifies that this proposed rule, if adopted, will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 10 CFR Part 9

Freedom of information, Penalty, Privacy, Reporting and recordkeepng requirements, Sunshine Act.

For the reasons set out in the preamble and under authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is proposing to adopt the following amendments to 10 CFR Part 9.

PART 9—PUBLIC RECORDS

1. Authority: Sec. 161, Pub. L. 83–703, 68 Stat. 948 (42 U.S.C. 2201); sec. 201, Pub. L. 93–438, 88 Stat. 1242 (42 U.S.C. 5841). Subpart A also issued under 5 U.S.C. 552; Subpart B also issued under 5 U.S.C. 552a; Subpart C also issued under 5 U.S.C. 552b.

2. Section 9.1 is revised to read as follows:

§ 9.1 Scope.

The regulations in this part:

(a) Implement the provisions of the Freedom of Information Act, 5 U.S.C. 552, with respect to the availability to the public of Nuclear Regulatory Commission records for inspection and copying, (b) implement the provisions of the Privacy Act of 1974, 5 U.S.C. 552a, with respect to disclosure and availability of certain Nuclear Regulatory Commission records maintained on individuals; (c) implement the provisions of the Government in the Sunshine Act, 5 U.S.C. 552b, with respect to opening Commission meetings to public observation; and (d) describe procedures with respect to the production of agency records, information, or testimony in response to subpoenas or demands of courts or other judicial or quasi-judicial authorities in state and Federal proceedings.

3. Section 9.1a is revised to read as follows:

§ 9.1a Subparts.

Subpart A sets forth special rules applicable to matters pertaining to the Freedom of Information Act. Subpart B sets forth special rules applicable to matters pertaining to the Privacy Act of 1974. Subpart C sets forth special rules applicable to matters pertaining to the Government in the Sunshine Act. Subpart D sets forth procedures to be followed by all NRC personnel and contract employees who have received subpoenas or other demands by judicial or quasi-judicial authorities calling for the production of NRC agency records or the disclosure of information or testimony.

4. In § 9.12, paragraph (b) is revised to read as follows:

§ 9.12 Production or disclosure of exempt records.

* * * * *

(b) NRC personnel and NRC contractors from whom a record exempt from disclosure is sought by non-judicial means shall follow the procedure specified below. Where the record is sought by judicial or similar process, NRC personnel and contractors shall follow the procedure specified in Subpart D:

(1) If an exempt record is sought from NRC personnel by non-judicial means, the request shall promptly be forwarded to the Director, Office of Administration, who shall process the request as provided in this part or take such other action as may be appropriate.

(2) If an exempt record is sought from an NRC contractor by non-judicial means, the request shall promptly be forwarded to the NRC contracting officer administering the contract who will then follow the procedure specified in paragraph (b)(1) of this section.

5. Subpart D (§§ 9.200 thru 9.204) is added to read as follows:

Subpart D—Production or Disclosure in Response to Subpoenas or Demands of Courts or Other Authorities

Sec.
9.200 Scope of subpart.
9.201 Production or disclosure prohibited unless approved by appropriate NRC official.
9.202 Procedure in the event of a demand for production or disclosure.
9.203 Procedure where response to demand is required prior to receiving instructions.
9.204 Procedure in the event of an adverse ruling.

Subpart D—Production of Disclosure in Response to Subpoenas or Demands of Courts of Other Authorities

§ 9.200 Scope of subpart.

(a) This subpart sets forth the procedures to be followed when a subpoena, order, or other demand (hereinafter referred to as a "demand") of a court or other judicial or quasi-judicial authority is issued for the production of NRC agency records, involving licensing, regulation, or enforcement activities, disclosure of information or testimony regarding such records, or information which involves:

(1) Any material contained in the files of the NRC;

(2) Any information relating to material contained in the files of the NRC; or

(3) Any information or material acquired by any person while such person was an employee of the NRC as a part of the performance of that person's official duties or because of that person's official status.

(b) For purposes of this subpart, the term "employee of the NRC" includes all NRC personnel as that term is defined in § 9.2, including NRC contractors.

(c) This subpart is intended to provide instructions regarding the internal operations of the NRC and is not intended, and does not, and may not, be relied upon to create any right or benefit, substantive or procedural, enforceable at law by a party against the NRC.

§ 9.201 Production or disclosure prohibited unless approved by appropriate NRC official.

No employee or former employee of the NRC shall, in response to a demand of a court or other judicial or quasi-judicial authority, produce any material contained in the files of the NRC or disclose through testimony or other means any information relating to material contained in the files of the NRC, or disclose any information or produce any material acquired as part of the performance of that employee's official duties or official status without prior approval of the General Counsel of NRC.

§ 9.202 Procedure in the event of a demand for production or disclosure.

(a) Whenever a demand is made upon an employee or former employee of the NRC for the production of material or the disclosure of information described in § 9.200, that employee shall immediately notify the General Counsel of NRC. If the demand is made upon a regional NRC employee or former employee, that employee shall immediately notify the Regional Counsel who, in turn, shall immediately request instructions from the General Counsel.

(b)(1) If oral testimony is sought by the demand, a summary of the testimony desired must be furnished to the General Counsel by an affidavit or, if that is not feasible, a statement by the party seeking the testimony or the party's attorney. This requirement may be waived by the General Counsel in the case of a demand by a grand jury, or other appropriate circumstances.

(2) The General Counsel may request a plan from the party seeking discovery of all demands that reasonably foreseeable, including but not limited to, names of all NRC personnel from whom discovery is or will be sought, areas of inquiry, length of time away from duty involved, and identification of documents to be used in each deposition, where appropriate.

(c) The General Counsel will notify the employee and such other persons as circumstances may warrant of his decision on the matter.

§ 9.203 Procedure where response to demand is required prior to receiving instructions.

If a response to the demand is required before the instructions from the General Counsel are received, a U.S. attorney or NRC attorney designated for the purpose shall appear with the employee or former employee of the NRC upon whom the demand has been made, and shall furnish the court or other authority with a copy of the regulations contained in this subpart and inform the courts or other authority that the demand has been, or is being, as the case may be, referred for the prompt consideration of the appropriate NRC official and shall respectfully request the court or authority to stay the demand pending receipt of the requested instructions. In the event that an immediate demand for production or disclosure is made in circumstances which would preclude the proper designation or appearance of a U.S. or NRC attorney on the employee's behalf, the employee shall respectfully request the demanding authority for sufficient time to obtain advice of counsel.

§ 9.204 Procedure in the event of an adverse ruling.

If the court or other judicial or quasi-judicial authority declines to stay the effect of the demand in response to a request made in accordance with § 9.203 pending receipt of instructions, or if the court or other authority rules that the demand must be complied with irrespective of instructions not to produce the material or disclose the information sought, the employee or former employee upon whom the demand has been made shall respectfully decline to comply with the demand, citing these regulations and *United States ex rel Touhy* v. *Ragen*, 340 U.S. 462 (1951).

Dated at Washington, DC, this 3d day of July, 1984.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,
Secretary for the Commission.

PART 9

PUBLIC RECORDS

STATEMENTS OF CONSIDERATION

33 FR 14531
Published 9/27/68
Effective 10/27/68

On June 29, 1967, the Atomic Energy Commission published in the FEDERAL REGISTER (32 F.R. 9213) amendments of its regulations, 10 CFR Part 1, Statement of Organization, Delegations, and General Information; 10 CFR Part 2, Rules of Practice; 10 CFR Part 3, Rules of Procedure in Contract Appeals; and 10 CFR Part 9, Public Records, which effectuated the provisions of Public Law 89-487, as amended and codified by Public Law 90-23 (5 U.S.C. Sec. 552), referred to as the Public Information Act of 1966.

Because these rules related solely to agency organization and practice and procedure, the Commission found that notice of proposed rule making and public procedure thereon were unnecessary and good cause existed to make the amendments effective on July 4, 1967. However, since these amendments were designed to provide information and guidance to members of the public regarding the availability of AEC records, the Commission invited all interested persons to submit written comments or suggestions regarding these amendments within 90 days after their effective date. After careful consideration of the comments received in response to the invitation and other factors involved, the Commission has adopted the amendments to 10 CFR Part 9 set forth below.

The present § 9.1 provides in part that Part 9 was not intended to limit any programmatic distribution of AEC information to the public. This section has been amended to state explicitly what was only implicit in the present § 9.1, namely that Part 9 is not intended to affect the dissemination or distribution of AEC or contractor originated information to the public pursuant to any AEC public, technical or other information program or policy, nor is it intended to restrict or limit the free flow of information between the AEC and its contractors or between the AEC and a Government agency. The amendment also adds a sentence to clarify that Part 9 applies to all AEC records, regardless of the date of the record.

The definition of "Record" in § 9.2(e) has been clarified with respect to the type of documentary material that constitutes an AEC record. The clarification will remove any inconsistency between this section and § 9.4.

Section 9.4 has been revised to be compatible with the amended § 9.2(e). Under the revision, it is made clear that records possessed by the AEC include those which may be in the physical possession of others.

The present § 9.5(a)(2)(ii) provides as an example of the type of record exempt under § 9.5(a)(2), "Negotiating techniques and positions including the fixed-fee policies of the AEC." Because this example is considered to be included in the example identified in subdivision (iii), "Bargaining positions and limitations," it has been deleted. As a consequence of this deletion, subdivisions (iii) and (iv) have been renumbered subdivisions (ii) and (iii).

Renumbered § 9.5(a)(2)(ii) has been revised to clarify that an AEC bargaining position or limitation in any matter involved in a negotiation is exempt from public disclosure until the negotiations are completed and the results are embodied in a record such as an executed contract which is not otherwise exempt from public disclosure.

The amendment of § 9.5(a)(4) is for the purpose of clarifying that trade secrets and business or financial information are exempt from public disclosure to the extent that the information would not customarily be released to the public by the originator.

The amendment of § 9.5(a)(5)(v) identifies documents awaiting patent review as one example of the type of record which is considered to be included in this exemption.

Subparagraph (6) of § 9.5(a) defines a clearly unwarranted invasion of personal privacy as meaning the disclosure of information which would be offensive to a reasonable man and which is not justified by a public policy to be considered of greater importance.

Subparagraph (10) of § 9.5(a) provides that records belonging to another Government agency are exempt from disclosure by the AEC but that requests for such records be promptly forwarded to the appropriate agency. Since such records may not be exempt from disclosure under the provisions of 5 U.S.C. section 552, the inclusion of these records in a list of records specifically exempt from disclosure by statute appeared inappropriate. Accordingly, subparagraph 10 has been transferred from paragraph (a) to a new paragraph (b). The new paragraph (b) has been amended for the purpose of additional clarity. The present paragraph (b) has been redesignated paragraph (c).

Section 9.7 has been revised to separate paragraph (a) into two paragraphs. The revised paragraph (a) identifies those records of the AEC which are available for public inspection only at the AEC Public Document Room.

The revised paragraph (b) of § 9.7 specifies that certain AEC records, presently available for public inspection only at the AEC Public Document Room, are also available for public inspection at the major operating field offices of the AEC.

A new paragraph (c) of § 9.7 incorporates the present paragraph (b), which specifies the hours during which the AEC Public Document Room is open and specifies the times during which the major operating field offices of the AEC will be open.

Section 9.8 has been completely revised to clarify the AEC procedures for making copies of records available to the public. Primarily the revision involves a reorganization of the content of the present section. Changes in § 9.8 of particular significance include a new provision for requesting records from the AEC when it is not convenient for a person to request the record from the AEC Public Document Room or a major operating field office of the AEC, and a new provision that, at the discretion of the AEC, requested records may be disclosed at AEC contractor's and subcontractor's facilities.

An amendment of § 9.9(f) (2) has been made to specify the AEC officials who make the determinations for waiving changes for record searches and the reproduction of copies of records.

Because these amendments relate solely to agency organization and practice and procedure, the Commission has found that notice of proposed rule making and public procedure thereon are unnecessary.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendments of 10 CFR Part 9 are published as a document subject to codification to be effective 30 days after publication in the FEDERAL REGISTER.

34 FR 9849
Published 6/26/69
Effective 7/25/69

On September 27, 1968, the Atomic Energy Commission published in the FEDERAL REGISTER (33 F.R. 14531) amendments of 10 CFR Part 9, Public Records, to become effective on October 27, 1968.

Because these amendments related solely to agency organization and practice and procedure, the Commission found that notice of proposed rule making and public procedure thereon were unnecessary. Subsequent to the publication of these amendments, comments were received regarding the amendments. After careful consideration of these comments and other factors involved, the Commission has adopted the amendments to 10 CFR Part 9 set forth below.

Subparagraph (6) of § 9.5(a) has been amended to delete the statement as to the meaning of "clearly unwarranted invasion of personal privacy" and to reinsert two sentences, one relating to the availability of records identified in subparagraph (6) to the person involved or his authorized representative and the other introducing examples of such records, which were inadvertently deleted in a previous amendment of this subparagraph. Comments received on the definition of "clearly unwarranted invasion of personal privacy" indicated that the definition was insufficiently clear to serve any useful purpose.

Subparagraph (7) of § 9.5(a), which exempts from public disclosure certain investigatory files compiled for law enforcement purposes, has been amended to provide two examples of the types of records included in this exempt category.

Paragraphs (a) and (c) of § 9.8 have been amended to clarify the procedure by which members of the public may request copies of AEC records and the procedures which the AEC will follow in responding to such requests. The significant change effected by this amendment is to provide that written requests for AEC records may be addressed to the managers of any of the Commission's major operating field offices in addition to the Secretary of the Commission.

The present § 9.9(f) (1) provides that no charges for locating copies of AEC records will be made for requested records on file in the AEC Public Document Room or in a comparable facility at a major field office of the AEC. The amendment clarifies this provision by providing that no charges for such service will be made for AEC records on file not only in the AEC Public Document Room but also those readily available at AEC Headquarters and at major operating field offices of the AEC.

Subparagraph (2) of § 9.9(f) has been amended to substitute the words "either's designee" in place of "authorized representatives" in order to conform with other provisions of Part 9.

The provisions of §§ 9.10(b) (1) and (3) and 9.10(c) have been amended to provide that designees of the General Manager, the Director of Regulation and the General Counsel may also take certain of the actions provided for in these provisions. Under this amendment the only action which is reserved exclusively for the General Manager or the Director of Regulation is notifying a requester of an exempt record that the record cannot be disclosed. The purpose of these amendments is to expedite the disposition of requests for copies of records exempt from disclosure under § 9.5(a).

The present § 9.10(d) has been amended to clarify that a decision of the General Manager or the Director of Regulation denying a request for the disclosure of an exempt record constitutes the final action of the AEC on the matter.

In addition, a number of editorial changes of a clarifying nature have been made.

Because these amendments relate solely to agency organization and practice and procedure, the Commission has found that notice of proposed rule making and public procedure thereon are unnecessary.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments of 10 CFR Part 9 are published as a document subject to codification to be effective 30 days after publication in the FEDERAL REGISTER.

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40 FR 7893
Published 2/24/75
Effective 2/24/75

PART 2—RULES OF PRACTICE
PART 9—PUBLIC RECORDS

Implementation of the Freedom of Information Act

Notice is hereby given of the adoption on February 19, 1975, of amendments to the Nuclear Regulatory Commission's regulations in Title 10, Chapter I, Code of Federal Regulations, Parts 2, "Rules of Practice", and 9, "Public Records". The amendments reflect certain provisions contained in the 1974 amendments to the Freedom of Information Act, Pub. L. 93–502, enacted November 21, 1974, and effective February 19, 1975. On January 15, 1975 the Atomic Energy Commission published proposed amendments to Part 9 to revise its schedule of fees for producing copies of records (40 FR 2714). Subsequently, in accordance with the Energy Reorganization Act of 1974, Pub. L. 93–438, the Nuclear Regulatory Commission (NRC) was established on January 19, 1975. The NRC assumed the licensing and related regulatory functions of the former Atomic Energy Commission. No comments were received on the proposed rule published on January 15, 1975.

The amendments set forth below establish procedures to be followed by persons seeking records from the NRC and the actions to be taken by the NRC with respect to such requests. The amendments provide that copies of records may be requested in person at the NRC Public Document Room and that written requests for copies of records shall be addressed to the Director, Office of Administration. If the Director, Office of Administration, determines that a request for records should be denied in whole or in part, that determination may be appealed to the Executive Director for Operations, who will make a decision whether or not to uphold the initial determination. For advisory committees, boards, panels, and offices reporting to the Commission, and the Office of the Executive Legal Director, the initial determination on a request for records shall be made by the head of such board, panel, or office, or the Advisory Committee Management Officer, as appropriate, rather than the Director, Office of Administration. An appeal of an adverse determination shall be made to the Commission instead of the Executive Director for Operations.

In conformity with the recent Freedom of Information Act amendments, the amendments set forth below provide for specified time limits within which Commission action, both initially and on appeal, must be accomplished. The Commission's regulations also are amended to correspond to the Freedom of Information Act amendments with respect to those records which are exempt from disclosure.

The amendments provide a schedule of fees to be charged for the production of records which reflect only the direct cost of the services provided. The charges for searching for requested records are lower than those which were published by the Atomic Energy Commission for comment on January 15, 1975 (40 FR 2714). The charge for record searches by clerical and administrative employees has been reduced from $5.70 per hour to $5.00 per hour, and the charge for searches by professional or supervisory employees has been reduced from $16.00 per hour to $12.00 per hour.

The amendments also make certain minor conforming changes in Part 9 required by the Energy Reorganization Act to reflect the establishment of the Nuclear Regulatory Commission on January 19, 1975.

Because the amendments relate to agency organization, practice, and procedure, or conform to the requirements of the Freedom of Information Act amendments of November 21, 1974, or the Energy Reorganization Act of 1974, the Commission has found that notice of proposed rule making and public procedure thereon are unnecessary, and good cause exists for making the amendments effective without the customary 30 day notice.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, and sections 552 and 553 of Title 5 of the United States Code, as amended by Pub. L. 93-502, November 21, 1974, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Parts 2 and 9 are published as a document subject to codification.

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40 FR 44483
Published 9/26/75
Effective 9/27/75

PART 9—PUBLIC RECORDS

Privacy Act Regulations

Notice is hereby given that the Nuclear Regulatory Commission has adopted amendments to its regulations in 10 CFR Part 9, Public Records, set forth below to implement the provisions of the Privacy Act of 1974, Public Law 93–579, enacted December 31, 1974, including, in particular, those provisions of the Privacy Act which require the promulgation of agency rules.

On August 12, 1975, the Nuclear Regulatory Commission published in the FEDERAL REGISTER (40 FR 33833–33838) for public comment, proposed amendments to 10 CFR Part 9, Public Records. Interested persons were invited to submit comments or suggestions for consideration in connection with the proposed amendments by September 12, 1975. Two responses concern § 9.95 of the regulations which relates to specific exemptions. A clarifying change in the wording of § 9.95 suggested by one commenter has been adopted in substance. A suggestion that § 9.95 be revised to describe the exemptions in each of the systems of records affected with greater specificity and that the revision be renoticed for further public comment has not been adopted. The Commission is of the opinion that it is impractical at this time to specify the exempt portions of records more precisely. In addition, the Commission has also made a number of minor clarifying changes in the text of the amendments. These changes are more particularly described as follows:

1. In § 9.54, the heading of paragraph (c) is changed to read "Verification of parentage or guardianship" in order to identify the subject of the paragraph more precisely. For purposes of further clarifying the text of paragraph 9.54(c), the word "legal" is inserted immediately before the word "guardian" where the latter word first appears and the word "of" is inserted immediately before the words "an individual judicially determined to be incompetent." The typo-

graphical errors in this paragraph are also corrected.

2. The following changes are made in § 9.65 for the purposes of accuracy and completeness. In paragraph (a), the last sentence is revised by inserting the words "or deny" between the words "grant access" and by changing the term "30 days" to read "30 working days." In the first sentence of paragraph (b), the term "30 days" is changed to read "30 working days." In paragraph (c)(1), the phrase "The Executive Director for Operations" is changed to read "The Executive Director for Operations, or his designee,". In paragraph (c)(2) the phrase "Executive Director for Operations" is changed to read "Executive Director for Operations, or his designee." wherever it appears.

3. In § 9.66, immediately following the first sentence in paragraph (a)(1), a new sentence is added for consistency which reads, "Unless the request presents unusual difficulties or involves extensive numbers of records, individuals shall be notified of determinations to authorize or refuse correction or amendment of a record within 30 working days after receipt of the request."

4. In paragraph 9.66(b) the term "30 days" is changed to read "30 working days"

5. The following changes are made in paragraph 9.66(c) for purposes of consistency and completeness. In paragraph 9.66(c)(1), the phrase "The Executive Director for Operations" is changed to read "The Executive Director for Operations, or his designee,". Paragraph 9.66 (c)(2) is redesignated as paragraph 9.66 (c)(3), and the phrase "the Executive Director for Operations" in that paragraph is changed to read "the Executive Director for Operations, or his designee,". Immediately following paragraph 9.66 (c)(1), a new paragraph (c)(2) is added which reads as set forth below.

6. In paragraph (a) of § 9.67, the term "30 days" is changed to read "30 working days".

7. For purposes of clarification and accuracy, paragraph (a) of § 9.69 is revised to read as set forth below.

8. In § 9.80, in the last sentence of paragraph (a)(7), the words "or if" immediately following the words "Federal Register" are deleted and are replaced by the word "and".

9. A centerhead "FEES" is inserted immediately preceding "§ 9.85 Fees."

10. In § 9.90, a typographical error in paragraph (a) is corrected.

11. For purposes of clarification and accuracy, the following changes are made in § 9.95. In the first sentence, the phrase "and from the provisions of this part other than § 9.61: is reworded to read "and are subject to the provisions of § 9.61 of this part:" In paragraphs (a), (b), (d), (f) and (j) the names of the systems of records are corrected to read as set forth below.

In accordance with the requirements of the Privacy Act of 1974, the amendments adopted herein must be in effect on or before September 27, 1975. In view of these requirements and in view of the fact that the amendments do not impose obligations on persons other than the Commission, the Commission has found that good cause exists for making the amendments effective without the customary 30 day notice.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552, 552a and 553 of Title 5 of the United States Code, the amendments to Title 10, Chapter I, Code of Federal Regulations, Part 9, set forth below are published as a document subject to codification.

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41 FR 20645
Published 5/20/76
Effective 5/20/76

PART 9—PUBLIC RECORDS

Amendments of Privacy Act and Freedom of Information Act Regulations

Paragraphs § 9.53(b), 9.65(b), 9.66(b), and 9.67(a) of the Nuclear Regulatory Commission's regulation, 10 CFR Part 9, require that appropriate legends be placed on the envelope or letter such as "Privacy Act Request," "Privacy Act Disclosure Accounting Request," "Privacy Act Correction Request," "Privacy Act Appeal—Denial of Access," "Privacy Act Correction Appeal," and "Privacy Act Statement of Disagreement." Paragraphs § 9.8(a) and 9.11(a), which pertain to requests under the Freedom of Information Act, also require appropriate legends on the envelope or letter.

The legends are intended to facilitate prompt handling of requests under the Privacy Act of 1974 and the Freedom of Information Act.

The amendments of §§ 9.53(b), 9.65(b), 9.66(b), 9.67(a), 9.8(a), and 9.11(a) set forth below suggest that these legends be placed on the envelope or letter, but make it clear that the use of such legends is not mandatory. Language is added to §§ 9.53(b), 9.65(b), 9.66(b), and 9.11(a), however, to provide notice that a request not clearly marked on the envelope and in the letter will be deemed not to have been received by the NRC until it is actually received by the appropriate office specified in 10 CFR Part 9.

Paragraphs 9.65(b) and 9.66(b) are amended as set forth below to increase the time for filing appeals from denials of access to records and denials of correction of records, to 60 days from date of receipt of an initial determination denying access to a record or a refusal to amend or correct a record. This is not a mandatory time limit, however, and appeals will be considered if filed after the 60-day period.

Because these amendments relate solely to minor matters, good cause exists for omitting notice of proposed rule making, and public procedure thereon, as unnecessary, and for making the amendments effective May 20, 1976.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552, 552a, and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 9, are published as a document subject to codification.

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41 FR 44997
Published 10/14/76
Effective 10/14/76

PART 9—PUBLIC RECORDS

Disclosure of Medical Records Under the Control of NRC

The Privacy Act of 1974 states that each agency must:

> Establish procedures for the disclosure to an individual upon his request of his record or information pertaining to him, including special procedure, if deemed necessary, for the disclosure to an individual of medical records, including psychological records, pertaining to him; (5 U.S.C. 552a(f)(3)).

Subpart B of the Nuclear Regulatory Commission's regulations 10 CFR Part 9 implements the Privacy Act of 1974 and provides in § 9.62(a) procedures for the disclosure of medical records under the control of NRC.

Section 9.62 provides that requests received by NRC pertaining to medical records under the control of NRC, with the exception of radiation exposure records, will only be made available to a physician of the requesting individual's choosing.

It is the Commission's view that § 9.62 (a) is overly restrictive and should be deleted, thereby permitting disclosure of medical records under the Commission's control directly to the requester. The amendment of § 9.62 set forth below deletes § 9.62(a) and redesignates § 9.62(b) as § 9.62(a).

Because this amendment relates solely to procedural matters good cause exists for omitting notice of proposed rule making and public procedure thereon as unnecessary. Since the amendment relieves from restrictions under regulations currently in effect, it may become effective without the customary 30-day notice.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552, 552a and 553 of Title 5 of the United States Code, the following amendment to Title 10, Chapter I, Code of Federal Regulations, Part 9 is published as a document subject to codification.

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42 FR 12875
Published 3/7/77
Effective 3/12/77

PART 9—PUBLIC RECORDS

Rules Governing Public Attendance at Meetings of the Nuclear Regulatory Commission

The Nuclear Regulatory Commission published a notice in the Federal Register on December 23, 1976 (41 FR 55880), announcing proposed amendments to Part 9 of its Rules of Practice to implement the open meeting requirements of the Government in the Sunshine Act of 1976, 5 U.S.C. 552b, Pub. L. No. 94-409 (the "Act"). Interested persons were requested to submit comments by February 1, 1977. Two written comments have been received, from Chairman Richardson Pryor of the House Subcommittee on Government Information and Individual Rights of the Government Operations Committee and from the Freedom of Information Clearinghouse. These comments have been considered, as have been suggestions received from other agencies and the Administrative Conference of the United States. The Commission has consulted with the Office of the Chairman of the Administrative Conference, as required by 5 U.S.C. 552b(g) of the Act. By this notice, final regulations are adopted.

These regulations make no major changes in the proposed rules, and the Statement of Considerations accompanying the proposed rules thus remains applicable. Minor changes have been made as the result of further analysis of the Act and of the Commission's experience during the past several months employing criteria similar to those in the Act to determine whether to open meetings to public attendance. 41 F.R. 55880. In several cases the proposed regulations have been altered to provide more direct guidance on the Act's application to specific items of Commission business.

The two commenters each questioned whether the definition of "Commission" in proposed § 9.101(a) left open the possibility that the Commission could circumvent the Act by delegating the power to act to assistants or employees and instructing them how to vote. The Commission acts only through the votes of a quorum of members present and may not use proxies for any vote. Its power to delegate certain authority (for example, to adopt minor amendments to its rules) to its Executive Director for Operations or other officials is not affected by the Act. It has delegated, pursuant to statute, certain authority for the conduct and review of adjudicatory proceedings to its Atomic Safety and Licensing Board and Appeal Board. The legislative history of the Act plainly supports the exclusion of these Boards (whose meetings would in any event be closed) from the definition of bodies subject to the Act.

Both commenters also questioned the proposed exclusion of "social or ceremonial" gatherings from the definition of meeting in proposed § 9.101(e). While the Commission acknowledges that agency decisions or covered discussions could occur at a "social" gathering, it is aware of the requirements of the Act and fully intends to observe the required discipline. The purpose of the exclusion is to prevent gatherings from being labeled meetings and made subject to the detailed procedural requirements of the Act solely because a quorum of Commissioners will be present. Section 9.102 of the rules adopted herein deals with the problem by making observance of these procedures mandatory whenever a quorum does conduct discussions that determine or result in the conduct or disposition of official agency business.

Public comment was specifically sought on the provision of proposed § 9.101(c) which specifically excludes from the definition of meeting "* * * briefings of the Commission by representatives of other agencies or departments of the United States Government or by representatives of foreign governments or international bodies, where such briefings are informational in nature and do not relate to any matter pending before the Commission." The two commenters questioned this provision, emphasizing those items of the legislative history of the Act providing that "all discussion relating to the business of the agency" was within the definition of meeting in 5 U.S.C. 552b(a)(2). H.R. Rep. 94–880, Part I, 94th Cong., 2nd Sess. (1976) at 8. Other legislative history, however, indicates that the Act was not intended to cover all gatherings of a quorum of agency members at which any discussion of agency business occurs. See, e.g., S. Rep. 94–354, 94th Cong., 1st Sess., (1975) at 18–19; 121 Cong. Rec. H. 9260 (daily ed. August 31, 1976) (remarks of Representative Fascell).

The amendment to the definition of meeting made by the Conference Committee appears clearly intended to make that definition less broad and less inclusive. See, S. Rep. 94–1178, 94th Cong., 2nd Sess. (1976) (Conference Report). Although the purpose of that amendment is not explained in the Conference Report or in subsequent floor discussion, it can only be interpreted as intending a limiting and narrowing of the House and Senate definitions. It seems most plausible to read that narrowing as excluding from the definition deliberations which do "concern" agency business but which are so tentative and general as not "to determine or result in" any joint agreement regarding future agency action. In this category might be placed briefings and even perhaps exploratory talks among Commissioners, provided, however, that such sessions are not designed or expected to result in any concensus among the Commissioners on any matter pending before the Commission. In supporting these views the Executive Secretary of the Administrative Conference of the United States ("ACUS") noted that to administer the fine distinction discussed above in accordance with the letter and the spirit of the Act will require diligence on the part of presiding officers and restraint on the part of individual Commissioners. The Commission agrees and intends to exercise the necessary diligence and restraint.

As the Commission remarked in the Statement of Considerations accompanying the proposed rules,

> * * * staff briefings of * * * the full Commission * * * purely to inform the Commissioners of matters of interest and general relevance to the performance of their duties * * * may well not come with the definition of "meeting" in the Act. (Nonetheless) * * * the Commission has determined to include such briefings of a quorum of the Commissioners within these regulations * * * because the Commission believes such briefings * * * are a vital portion of the Commission's supervision of its staff and of Commission business in general, and because of the presumption in favor of opening agency business to public observation established by the Act.
>
> The situation is quite different with regard to other briefings the Commission receives from time to time from sources outside the Commission. Where such briefings concern a specific item of Commission business such as a particular rulemaking or license application, then they properly are "meetings" and are treated as such in these regulations. However, some Commission briefings are by other agencies or by representatives of foreign governments and are not focused on specific items of Commission business, but are intended purely to provide general background information to the Commission. Often such briefings are on such sensitive topics that any application of the Act, even with the use of the mitigative procedures of that Act, would prevent the briefing from being held at all.

Experience in the past several months has demonstrated that such gatherings, although infrequent, do occur, particularly in connection with the Commission's export business and safeguards responsibilities. The inability of the Commission to participate in such gatherings would cause significant harm to the Commission's ability to carry out its responsibilities in several areas. The Commission continues to believe, for these reasons, that the definition of meeting contained in § 9.101(c) (with the minor amendment discussed below) is consistent with the Act.

Both commenters also suggested that, in determining whether to close particular meetings, the Commission must adopt a formal two-step procedure. The decision whether a specific exemption is available does not, in their view, aid in determining whether the public interest nevertheless requires a meeting to be open. Section 9.104(a) of the rules, like the proposals of several other agencies, gives presumptive but not conclusive force to the determination that an exemption is available in deciding the public interest question. The fact that a meeting does come within a specific provision of § 9.104(a) indicates that the Congress recognized a public interest in closing, not opening, meetings of this character. The Commission staff has been instructed to consider the public interest in recommending to the Commission whether or not to close particular meetings. The Commission believes that this internal procedure and the awareness of the Commissioners themselves and their advisors of public interest concerns will ensure adequate consideration of the public interest before any decision to close a meeting is made, without need for a formal procedure of the type proposed.

Both comments raised questions concerning the first example stated in proposed § 9.104(b). These comments interpreted the reference to *Brockway* v. *Department of the Air Force*, 518 F.2d 1184 (8th Cir. 1975), in the accompanying Statement of Considerations as an effort to create an exemption similar to Exemption 5 of the Freedom of Information Act, which the Commission recognizes was considered and rejected in the Sunshine Act. However, the Commission has no such purpose. In its view, the "Brockway" decision reflects a more basic consideration also embodied in Exemption 9(B) of the Sunshine Act, namely that the government has an inherent privilege to attempt to obtain information necessary for its functioning. 5 U.S.C. 552b(c)(9)(B) authorizes closing a meeting if opening it would substantially frustrate a proposed Commission action. In those few cases where needed information simply will not be provided to the Commission except in confidence, if the Commission does not close the meeting it would be forced to take action without that information and therefore may not have the required basis on which to proceed—a significant frustration of its action. While the Commission appreciates the contrary arguments, which were also suggested by the Administrative Conference comment, its experience has been that on those occasions when this exemption would be used the need for such information is pervasive and crucial to the Commission's decision. To abandon the exemption would be to risk error in decisions of great significance to the public.

Chairman Pryor also comments, with respect to the second example of § 9.104(b), that this reasoning may not be applied where the possible effect is upon the actions of others. An example of such a situation might be where anticipated discussion would influence the outcome of pending or reasonably anticipated litigation in which the Commission was not or would not be a party. The Commission agrees that in such a situation, this exemption would not apply.

Section 9.104(a)(10) provides for closing of meetings that concern, inter alia, the Commission's participation in a civil action or proceeding. It should be noted that this also covers discussions about whether to initiate such an action or the possibility that outside parties might initiate such a proceeding against the Commission. See, S. Rep. 94–354, 94th Cong., 1st Sess. (1975) at 26; H.R. Rep. 94–880, Part I, 94th Cong., 2nd Sess. (1976) at 12. This point was also noted by the Administrative Conference.

Both commenters objected to the wording of § 9.105(c), which has been changed to meet their objections. Similarly, § 9.108(a) has been altered, inter alia, to reflect a comment by Chairman Pryor.

The comments received from the Executive Secretary of the Administrative Conference of the United States pointed out that the procedure provided for in proposed § 9.108(c) was not required by the statute. The Commission recognizes its right to delegate the responsibility for reviewing transcripts, S. Rep. 94–354, supra at 31, and see below, but believes that in the early period of implementation of the Act, it is appropriate to retain that responsibility for itself to ensure that it is carried out in a responsible and consistent manner. We note that the attachment to the comments of the Chairman of the Subcommittee on Government Information and Individual Rights appears to approve as appropriate the suggested procedures.

OUTLINE OF CHANGES TO PROPOSED REGULATIONS

Section 9.101(c) has been slightly changed to provide that briefings must not be "conducted" with reference to specific matters before the Commission to be excluded from the definition of meeting.

Two changes have been made in § 9.103. A sentence has been added to make it clear that the statements of Commissioners or NRC employees at open meetings do not represent final determinations or beliefs. This simply recognizes that during discussions before the Commission or any other deliberative body positions are often expressed not as reflections of fixed determinations but for purposes of argument or to obtain further exploration of certain points. Also, it is not uncommon for a position that was tentatively stated during a meeting to be abandoned upon further reflection. This addition restates the established rule that the Commission speaks formally only through its written opinions, orders or other documents. The other change to § 9.103 is intended to simplify enforcement of the portion of the rule prohibiting use of unauthorized recording equipment or cameras at open meetings.

A minor change was made to § 9.104(a) to delete an unnecessary reference to § 9.106 in the first sentence. Several clarifications were made to the specific exceptions in § 9.104(a). Section 9.104(a)(4) was clarified to include a reference to 10 CFR 2.790(d) in which the Commission defines certain information about safeguards for licensed special nuclear material and details of physical security measures for licensed facilities as proprietary information.

Section 9.104(a)(5) was changed to reflect that the exemption is available in circumstances involving a possible imposition of a civil penalty upon any person or possible revocation of any license. "Person" as used therein includes a corporation. S. Rep. 94–354, 94th Cong., 1st Sess. (1975) at 22. Both of the proposed changes reflect sanctions the Commission may inflict that have severity intermediate between accusation of a crime and formal censure. It would be anomalous to close meetings dealing with sanctions at the ends of the spectrum while leaving open meetings involving intermediate sanctions.

Section 9.104(a)(7) was changed to include specific reference to the Atomic Energy Act and the Energy Reorganization Act. The numbering of the subsections was changed by inserting a new § 9.104(a)(8) which will remain vacant and renumbering proposed § 9.104(a)(8) as § 9.104(a)(9), and § 9.104(a)(9) as § 9.104(10). This is designed to keep the numbering system of the regulations similar to that of the Act.

Section 9.104(a)(10) (proposed § 9.104(a)(9)) has been changed by adding Commission participation in a proceeding before another administrative agency to the list of varieties of proceedings. Considerations identical to those relating to participation before a court are applicable to such participation and it should receive similar treatment.

The two examples of possible applicability of 5 U.S.C. 552b(c)(9)(B) in the proposed regulations have been slightly changed and a third example added. The added example, dealing with communications with other agencies including the Executive Branch and the Congress is based upon a dialogue on the Senate floor between Senators Percy and Chiles, 121 Cong. Rec. S. 19442 (daily ed. November 6, 1975).

Section 9.105(c) has been slightly changed in response to comments received to make it clear that information may be withheld only if that information falls within one of the specific categories mentioned and a specific exemptive provision or provisions is cited by the Commission.

The public notice provisions of proposed § 9.107(c) have been somewhat modified to eliminate any possible implication that the Secretary would be obligated to perform useless acts such as mailing notices to persons who cannot possibly receive those notices until after the meeting takes place. Also, the requirement that the Secretary maintain a telephone recording system to give out the announcement has been deleted as of this time, although the practice may be introduced at some future date.

Section 9.108(a) has been changed in two respects. First, it now clearly provides, as recommended in a comment, that the General Counsel's certification must be made prior to the meeting in question. Second, a provision has been added permitting the certification not to be made public for the same reasons other information may be withheld from the public. Section 9.108(b) has been slightly changed to provide that the fee schedule used for requests for documents under the Freedom of Information Act shall also apply to requests made under the Sunshine Act. Minor changes have been made in the wording of the § 9.108(c), and there has been added an explicit reservation of the Commission's right to delegate the responsibilities provided for in that section.

A new § 9.108(d) has been added providing for the release of transcripts, recordings or other information which may no longer be justifiably withheld from the public.

In accordance with section 161 of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552b(g) and 553, 10 CFR Parts 2, 7, and 9 are amended.

42 FR 62471
Published 12/13/77
Effective 12/13/77

PART 9—PUBLIC RECORDS

Release of Transcripts of Closed Commission Meetings

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Commission is amending its regulations to remove the requirement that counsel attend all closed Commission meetings to advise the Commission on possible withholding of transcripts of those meetings. It is no longer necessary for counsel to attend all closed Commission meeting due to Commission experience in operation under the Sunshine Act. Determination as to which, if any portions of transcripts are to be withheld from the public may now be made by the Commission or by the Commission's Secretary.

EFFECTIVE DATE: December 13, 1977.

FOR FURTHER INFORMATION CONTACT:

Stephen Ostrach, 202–254–8017.

SUPPLEMENTARY INFORMATION: Experience in operation under the Government in the Sunshine Act, 5 U.S.C. 552b, has shown that it is no longer necessary for counsel to attend all closed Commission meetings. Determination of which, if any, portions of transcripts or other items of information may be withheld pursuant to 10 CFR 9.104, may now be made by the Commission's Secretary, based upon prior Commission policy guidance, the advice of the Office of the General Counsel, and consultation with the Commission. The Commission has therefore decided to amend 10 CFR 9.108(c). This action is not intended to have any substantive effect on Commission policies under the Sunshine Act.

Accordingly, and because this amendment relates to matters of agency organization and practice, general notice of proposed rulemaking is unnecessary.

43 FR 13055
Published 3/29/78
Effective 3/29/78

PART 9—PUBLIC RECORDS

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Commission is amending its regulations governing conduct at its open meetings to allow members of the public to make electronic sound recordings of those meetings. Use of other electronic equipment such as camera flashes will continue to require the advance approval

of the Commission's Secretary.

EFFECTIVE DATE: March 29, 1978.

FOR FURTHER INFORMATION CONTACT:

Stephen S. Ostrach, 202-254-8017.

SUPPLEMENTARY INFORMATION: The Commission has determined that the use of small electronic sound recorders by persons in attendance at its open meetings would not hinder the conduct of business and might be an additional step to increase public understanding of the Commission's actions. Accordingly the Commission has determined to amend 10 CFR 9.103 to reflect this. Use of more intrusive electronic equipment such as television cameras, or flash guns will continue to require the advance approval in writing of the Secretary of the Commission.

Because this amendment relates solely to matters of internal agency practice, general notice of proposed rulemaking is unnecessary.

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43 FR 37420
Published 8/23/78
Effective 8/23/78

PART 9—PUBLIC RECORDS

Open Meetings

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Commission is amending its rules to make explicit the present practice of not permitting parties to cite statements made at open meetings by Commissioners or Commission employees in support of argument presented to its adjudicatory boards.

Open meetings of the Commission are not part of the formal or informal record of decision in Commission proceedings. It would inhibit the candid and spontaneous nature of the discussions at such meetings if every statement made could be quoted and relied upon in subsequent proceedings.

Currently the Commission's regulations prohibit filing papers based upon such statements with the Commission itself. The same reasons that support a bar on such filings with the Commission also support a prohibition against filings with the subordinate adjudicatory bodies in the Commission. The Commission has decided to amend its regulations accordingly.

EFFECTIVE DATE: August 23, 1978.

FOR FURTHER INFORMATION CONTACT:

Stephen S. Ostrach, Esq., Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, 202-634-3224.

SUPPLEMENTARY INFORMATION: Because this amendment relates to matters of internal agency practice, general notice of proposed rulemaking is unnecessary.

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44 FR 15998
Published 3/16/79
Effective 4/16/79

PART 9—PUBLIC RECORDS

Waiver or Reduction of Fees for Searching and Reproduction of Records

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: This rule amends the Commission's regulations "Public Records" by adding a new section "Waiver or Reduction of Fees." These amendments reflect the requirements of the Freedom of Information Act that documents shall be furnished without charge or at a reduced charge where an agency determines that waiver or reduction of the fee for searching and reproduction of records is in the public interest because furnishing the information can be considered as primarily benefiting the general public.

EFFECTIVE DATE: This rule becomes effective on April 16, 1979.

FOR FURTHER INFORMATION CONTACT:

Mr. J. M. Felton, Director, Division of Rules and Records, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (telephone 301-492-7211).

SUPPLEMENTARY INFORMATION: On March 31, 1977 the Commission published in the FEDERAL REGISTER (42 FR 17131) proposed amendments to its regulation "Public Records," 10 CFR Part 9, which would add a new § 9.14a, "Waiver or Reduction of Fees." At the request of the Union of Concerned Scientists, the comment period was extended to May 23, 1977.

Comments on the proposed rule were received from the Union of Concerned Scientists (UCS) and the Rochester Gas and Electric Corporation (RG&E).

DISCUSSION OF COMMENTS

1. *Adequacy of Standards for Making Determinations to Waive or Reduce Fees.* Section 9.14a(c) of the proposed rule required a person who requests the NRC to waive or reduce fees to provide information concerning such matters as the intended use of the records, how the information would be disseminated to the public, the size of the public to be benefited, and any financial benefit the requester may receive from the use of the records. The rule repeated the Congressional mandate contained in the FOIA that records shall be furnished without charge or at a reduced charge where the agency determines "that waiver or reduction of the fee is in the public interest because furnishing the information can be considered as primarily benefiting the general public." In making this determination, the proposed rule provided that the NRC would, based upon the information submitted by the requester, balance whether the benefit to the public outweighs the cost to the public.

In their comments, UCS stated that the governing criteria were vague and subject to arbitrary agency determinations, and that the NRC should develop criteria to be applied in specific cases. In response to the comments, paragraph (c) of § 9.14a has been revised to require the requester to show how the intended use of the records is reasonably likely to:

(i) Result in actions to maintain or enhance the public's health, safety, or the quality of the environment;

(ii) Result in improved regulatory processes;

(iii) Reduce the cost of providing a government service;

(iv) Contribute substantially to public debate on an important policy issue; or

(v) Contribute substantially to matters of historical importance. In addition, a new paragraph (d) has been added to § 9.14a which specifies those situations in which a public benefit would not normally result. Finally, a new paragraph (e) has been added which provides that based upon the criteria in paragraph (d) and the information furnished by the requester in response to paragraph (c), the NRC will determine if waiver or reduction of the fee is in the public interest because furnishing the information can be considered as primarily benefiting the general public.

2. *Automatic Waiver of Fees for Public Interest Groups.* UCS proposed that non-profit organizations whose mission is to protect or enhance the public health, safety, and welfare, are automatically entitled to a waiver or reduction of fees. The Commission does not agree, and believes the proper statutory criterion is whether production of the records would primarily benefit the general public; that is, the focus of the decision to waive or reduce fees should be on the intended use of the records, and not the requester's organization affiliation, the organization's tax exempt status, or the purpose of the organization. It is recognized, however, that many non-profit organizations, whose mission is to protect or enhance the public health and safety, would qualify for a waiver or reduction of fees. In hearings before the Senate Subcommittee on Administrative Practice and Procedure in October, 1977, the head of the Freedom of Information Committee and other Department of Justice witnesses indicated in response to questions by Senator Abourezk that, although the decision would have to be made on a case-by-case basis, there would be a presumption that fees should be waived for public interest groups and media representatives. In light of these considerations, a new provision has been added to the proposed effective rule as § 9.14a(f) which provides that the NRC, in absence of a specific request for a waiver or reduction of fees, may waive or reduce the fees if it determines, based upon infor-

mation furnished by the requester in his request for access to records, that production of the records would primarily benefit the general public. This provision allows the agency to waive or reduce fees where the information provided in the request letter indicates that the requester is likely to use the records in a manner which primarily benefits the general public. It is designed to alleviate the formal showing by requester organizations that they meet the requirements of § 9.14a where it is obvious a fee waiver or fee reduction is justified under the circumstances.

3. *General Waiver Provisions.* With respect to the general waiver provisions set forth in § 9.14a(b) of the proposed rule, the Rochester Gas and Electric Corporation challenges the right of the NRC to waive fees for searches which do not exceed four hours or for reproduction costs which do not exceed $10.00. The basis for the company's claim are that there has been no showing that the general waiver provisions are in the public interest and that it is unfair to assess taxpayers for work done by a public employee for the benefit of a private party. The purpose of the general waiver provisions was to eliminate the costs of billing and processing payments and responding to requests for a waiver of fees when these costs to the government were relatively small in relation to the amount of staff time that would be required to process a fee waiver request or. to collect reproduction costs. In view of the NRC's practice of granting access to records by placing copies of the records in NRC Public Document Room or a Local Public Document Room, the provision granting waiver of reproduction costs not in excess of $10.00 has been eliminated from the effective rule. The Commission believes, however, that it is in the public interest to waive the minimal costs encompassed by the search fee waiver provisions, and the effective rule continues to contain this provision. The Rochester Gas and Electric Corporation also challenges the propriety of automatically waiving search fees as provided in § 9.14a(b)(4) of the proposed rule when no documents subject to the request are located or when no documents are located which can be disclosed to the requester. The Commission believes that this situation is now adequately addressed by the revised fee waiver criteria set forth in § 9.14a, and this provision has been eliminated from the effective rule.

4. *Relevancy of Information Required To Be Submitted by a Requester for Waiver or Reduction of Fees.* UCS questions the right of the NRC to require organizations to submit information in order to qualify for a waiver of fees stating that "it is the responsibility of the agency to initially decide whether a primarily public benefit will ensue from the release of the information" and the request "need only raise a substantial question as to whether the release of the information will 'primarily benefit the general public' ". As noted above in item 2, § 9.14a(f) provides that the NRC may waive fees on its own initiative, and the information required by § 9.14a(b) would only have to be submitted when the agency has concluded that the request, on its face, does not automatically warrant waiver or reduction of fees. Under these circumstances, the Commission believes that the burden of proof properly shifts to the requester to provide NRC with sufficient information to justify that production of the records will primarily benefit the general public. UCS also questions the ability of the requester to comply with certain information requirements § 9.14a(c) of the proposed rule and challenges the relevancy of others. These are discussed as follows:

A. UCS questions the ability of the requester to respond to the requirements in § 9.14a(c)(1) of the proposed rule regarding the "intended use of the records", and states that the exact use cannot be determined until the requested documents are reviewed. The information required by this provision is *intended* use of the records, not *exact* use. Failure of a requester to have some idea in mind as to how the records requested will be used would be persuasive evidence that the requester is on a fishing expedition and that providing the records would not primarily benefit the general public. This provision has been retained in the effective rule.

B. UCS also questions the ability of a requester to respond to the requirement "why all the requested documents are necessary to accomplish the requester's intended use" (§ 9.14a(c)(2) of the proposed rule). UCS points out that in most FOIA cases, "all" the requested documents are never necessary. The Commission agrees with this comment and feels that this information is not necessary. Where an issue is raised regarding the scope of a request, it has been the experience of the Commission that a negotiated resolution can be reached with the requester.

C. UCS questions the requirement to provide information concerning how the documents will be reviewed or analyzed and the results thereof disseminated to the public (§ 9.14a(c)(3) of the proposed rule), and argues that a specific use cannot be meaningfully presented until the documents are read. As stated in item 3.A above, the Commission believes there should be an intended use of the documents at the time a request for waiver is made. Further, the requirement for review and analysis of the documents reinforces that belief, as provided in § 9.14a(d)(5) of the effective rule, that the intent to distribute copies of the records to the public does not, by itself, constitute public benefit.

D. UCS, while questioning the relevancy of the requirement to provide information regarding what financial benefit, if any, the requester will receive from use of the requested records (§ 9.14a(c)(6) of the proposed rule), acknowledges the relevancy of the requirement if direct financial benefit is the only motivating factor in making the request. The ability of the requester to pay for the records also was acknowledged by Congress as being relevant to a determination of whether to waive or reduce fees. The Senate Report on the 1974 Amendments to the FOIA indicated that if a requester was indigent, a waiver or reduction of fee would be in the public interest. The Commission has, however, deleted the requirement regarding the requesters "willingness to pay" for the requested documents.

It should be noted that the specific items of information required to be furnished by requesters is based upon the guidelines contained in the Attorney General's Memorandum on the 1974 Amendments. In the Justice Department's recent testimony before the Abourezk Subcommittee, it was stated that these guidelines were coordinated with both the House and Senate committees responsible for the FOIA legislation.

The Commission believes that in the absence of clear Congressional guidance as to what was the intent of the term "primarily benefiting the general public", and in light of the diversity of requesters and type of records requested, the standards and criteria set forth in § 9.14a of the effective rule are sufficient to assure that the agency makes a fair and equitable determination with respect to any request for a waiver or reduction of fees.

5. *Adequacy of Procedures for Processing Requests for Waiver or Reduction of Fees.* UCS alleges that the proposed rule did not set forth an adequate administrative structure to assure fair and efficient processing of FOIA requests and requests for waiver or reduction of fees. UCS questions whether NRC has the right, if a request for records does not qualify for a waiver of fees, to deem the request not received, for purposes of complying with the ten-day FOIA response deadline, until a deposit equal to the estimated costs is received or the requester has agreed to bear the anticipated costs. UCS also states that requesters should be allowed to initiate fee waiver requests on appeal.

In response to UCS's comments, a new § 9.14b has been added to the effective rule which specifies the procedures which will be followed in processing an FOIA request for a waiver or reduction of fees. The procedures provide that if the request involves more than four hours of search time, and the requester does not qualify for a waiver of fees under § 9.14a(f), the NRC will notify the requester within 10 working days of the estimated costs of complying with the request. Thereafter, the requester may agree to pay for the records or request a waiver or reduction of fees. If the NRC refuses to waive or reduce the fees, it will provide a statement to the requester as to why the request does not meet the requirements of § 9.14a, and this determination may be appealed to the EDO or to the Commission, as appropriate. Where the request does qualify for waiver or reduction of fees, § 9.14b provides that records will be promptly provided.

The Commission believes that the new procedures for processing requests are responsive to UCS's concerns and provide a reasonable balance between the rights of the requester, the resources available to the NRC, and the rights of the general public. The Commission further believes that the NRC has an obligation not to expend public funds to search for records requested under the FOIA when the request does not either qualify for an automatic waiver of fees or the requester does not agree to pay the costs of the search. Congress, in permitting agencies to charge fees to cover costs of searching for records, implied that where production of the records would not primarily benefit the general public, search costs should be assessed. It would be a misuse of public funds to divert the staff from other important activities to conduct a search for records which a requester may never agree to pay for or may never make the showing that waiver of the fees is justified under the circumstances. In view of these considerations, the Commission continues to believe that a request for access to records should not be deemed to have been received until the fee issue is resolved by the requester either agreeing to pay for the records or by qualifying for a waiver or reduction of fees. In addition, the Commission does not agree with UCS's recommendation that documents be made available to the requester at the initial stage and that a requester then be permitted to request a fee waiver on appeal "even though no such initial request was made." The Commission has, however, agreed on a trial basis to provide in § 9.14b(d) that, in those cases where a waiver of fees was requested and denied and the requester agreed to bear the estimated cost, the requester may, within 30 days of receipt of the requested documents, resubmit a request for a waiver or reduction of fees if the receipt of the documents has materially changed the information originally furnished by the requester.

With respect to the waiver or reduction of fees for reproduction costs, the majority of NRC requesters, as a matter of practice, accept access to requested records at the NRC Public Document Room in Washington, D.C. or at a Local Public Document Room in cases where the requested documents pertain to a specific facility. The requester may then examine the records which have been made available, and make copies of just those records in which he is interested. The Commission believes this procedure is in the public interest and represents a reasonable balance between the rights of the public and the rights of the individual requester. The Commission also believes that this procedure is in accord with the broad purpose of the FOIA by providing general public access to agency records. Under the circumstances when access to records can be provided to a requester at a PDR or LPDR, to also waive reproduction costs would result in a private benefit only to the requester. This practice has now been incorporated into the regulations by adding a sentence to § 9.10(a) of the effective rule that provides that copies of documents disclosed in response to FOIA requests will normally be placed in the NRC PDR or local PDR, and by providing in § 9.14a(g) that the NRC will not waive reproduction costs for documents located in the PDR or LPDR in the absence of a compelling reason to do so. A "compelling reason" could be, for example, if the requester were both indigent and required the documents for intervention in an NRC licensing proceeding.

6. *Charging Professional and Clerical Rates for Searching.* UCS states that the present rule does not adequately indicate when clerical rates or when professional rates for search will be applied, and recommends that professional search charges should only be applied in those instances where it is absolutely essential for professionals to search for documents due to the nature and content of the requested document. The Commission believes that the proposed rule, as published, is adequate, and that this matter is properly left to the discretion of the responsible operating official. Decisions regarding who will conduct the search are dependent upon subject matter of the request, familiarization of staff with subject matter, and the necessity to assure an adequate and timely search within the FOIA statutory deadlines. FOIA requests received by the NRC are normally related to specific technical issues and, in many cases, only a member of the professional staff is capable of assuring that all records within the scope of the request are identified. The diversity of the subject matter of FOIA requests received by NRC would make it virtually impossible to establish general criteria applicable to all requests. It is expected, however, that the responsible operating official will use clerical staff to conduct the search where it is feasible to do so in order not to unnecessarily divert the technical staff from their regulatory functions or to increase costs to the requester.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 9 are published as a document subject to codification.

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44 FR 50804
Published 8/30/79
Effective 8/30/79

10 CFR Part 9

Amendments to Appendix A—Requests for Declassification Review

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to substitute references to a new Executive Order (E.O. 12065) and its implementing directive (Information Security Oversight Office (ISOO) Directive No. 1) for the replaced Executive Order (E.O. 11652) and its implementing National Security Council (NSC) Directive. The amendments reflect E.O. 12065's availability of mandatory document declassification review procedures at anytime after classification rather than the previous 10-year period as well as other conforming changes. This action is being taken by NRC to reflect E.O. 12065's intent to increase openness in government by limiting classification and accelerating declassification while improving protection of national security interests.

EFFECTIVE DATE: August 30, 1979.

FOR FURTHER INFORMATION CONTACT: J. M. Felton, Director, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Phone: 301-492-7211.

SUPPLEMENTARY INFORMATION: Notice is hereby given of the amendment of the Nuclear Regulatory Commission's Regulation, "Appendix A—Requests for Declassification Review," 10 CFR Part 9.

On June 28, 1978 the President issued Executive Order 12065 which supersedes a prior Executive Order (E.O. 11652). The new order is intended to increase openness in government by limiting classification and accelerating declassification. The Executive Order also establishes an Information Security Oversight Office (ISOO) to assume the previous responsibilities of the Interagency Classification Review Committee (ICRC).

The Nuclear Regulatory Commission is amending its regulations to substitute reference to E.O. 12065 and its implementing directive (ISOO Directive No. 1) for previous E.O. 11652 and its implementing NSC directive references. The minor amendments also reflect E.O. 12065's availability of mandatory document declassification review procedures at anytime after classification rather than the previous 10-year period. Likewise, the amendments change certain language in the regulation, to conform to the new Executive Order.

Finally, the new Executive Order abolishes a former appeal right under E.O. 11652 whereby a requester could have appealed to the ICRC. As a result, the appeal right formerly contained in section 3 of Appendix A, 10 CFR Part 9, has been deleted, with one exception. A right of appeal to the ISOO still exists with respect to decisions on declassification requests of information over 10 years old originated by the President, the White House Staff, committees or commissions appointed by the President, or by others acting on behalf of the President, including such information in the possession and control of the Administrator of the General Services Administration pursuant to 44 U.S.C. 2107 or 2107 note (E.O. 12065 section 3–503). Other minor changes have been made in Appendix A to improve the clarity of the regulation.

Because these amendments relate solely to minor procedural matters, and do not impose obligations on persons other than the Nuclear Regulatory Commission, good cause exists for omitting notice of proposed rulemaking, and public procedure thereon, as unnecessary, and for making the amendments effective on August 30, 1979, without the customary 30 days notice.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and Sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10 Chapter I, Code of Federal Regulations, Part 9 are published as a document subject to codification.

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45 FR 9729

Published 2/13/80
Effective 2/13/80

10 CFR Part 9

Procedure for Resubmitting Requests for Waiver or Reduction of Fees Under the Freedom of Information Act

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is issuing an amendment to 10 CFR Part 9, "Public Records". The amendment revises "Subpart A—Freedom of Information Act Regulations" to make permanent the present procedure which allows persons who have been denied a fee waiver or reduction of fees under the Freedom of Information Act to resubmit requests for such a waiver or reduction following receipt of the documents. The Commission has determined, based on the experience of the six-month trial period, that the procedure for resubmitting requests for fee waiver or reduction is not an undue burden on the staff, is in the public interest, and should be retained permanently.

EFFECTIVE DATE: February 13, 1980.

FOR FURTHER INFORMATION CONTACT: Joseph M. Felton, Director, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555 (Telephone: 301–492–7211).

SUPPLEMENTARY INFORMATION: On March 16, 1979, the Commission published amendments to 10 CFR Part 9 on the waiver or reduction of fees under the Freedom of Information Act (44 FR 15998). Those amendments contained a new paragraph 9.14b(d) which states:

> In those cases where a waiver of fees was requested and denied and the requester has agreed to bear the estimated cost, the requester may within 30 days of receipt of the requested documents resubmit a request for a waiver or reduction of fees if the receipt of documents has materially changed the information originally furnished by the requester pursuant to 9.14a(c). This paragraph (d) will become ineffective after December 17, 1979 such that no requests for reconsideration submitted after this date will be reviewed unless the Commission takes action to extend or make permanent this provision.

The Commission has determined, based on the experience of the six-month trial period, that the procedure for resubmitting requests for fee waiver or reduction is not an undue burden on the staff, is in the public interest, and should be retained permanently. The amendment provided below removes the final sentence of 10 CFR 9.14(d), thus removing the expiration date of the paragraph, and retains in force the procedure for resubmittals of requests for fee waiver or reduction.

The Commission finds that because the present rule is of a relieving nature, it is in the public interest to issue this rule without public comment, and good cause exists to make the rule effective immediately upon publication.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendment to Title 10, Chapter I, Code of Federal Regulations, Part 9 is published as a document subject to codification.

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45 FR 70225

Published 10/23/80

Effective 10/23/80

10 CFR Part 9

Revised Costs for the Reproduction of Agency Records

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations to reflect the new costs for the reproduction of records made available to the public. The revised rates reflect specific costs in a copying service contract that was awarded after competitive bidding.

EFFECTIVE DATE: October 23, 1980.

FOR FURTHER INFORMATION CONTACT: Lynn Scattolini, Chief, Public Document Room, Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: 202–634–3273.

SUPPLEMENTARY INFORMATION: Requests by the public for the reproduction of records at the NRC Public Document Room in Washington, DC, have traditionally been accommodated by a copying service contractor. The NRC recently solicited bids for a new contract, and a contract has been awarded to Literature Research Company. The changes in copying costs to the public which result from the letting of the new contract are reflected in the amendments below to paragraph (a) of § 9.14. In addition, paragraph (b) of § 9.14 has been revised to reduce the per page copying cost for documents made available at locations other than the Public Document Room. Further information on the services available at the Public Document Room are described in NUREG/BR–0004, Public Document Users Guide.

A single copy of this publication may be obtained after November 1, 1980, by writing to the U.S. Nuclear Regulatory Commission, Public Document Room, Washington, D.C. 20555.

Since these amendments reduce the costs for reproducing records, and because they reflect the specific costs in a copying service contract recently awarded after competitive bidding, notice of proposed rulemaking and public comment are unnecessary, and good cause exists to make the amendments effective upon publication in the **Federal Register**.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of Title 5 of the

United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 9 are published as a document subject to codification.

47 FR 4676
Published 2/2/82
Effective 2/2/82

10 CFR Part 9

Privacy Act Regulations; Notice of Exemptions; Correction

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule; correction and clarification.

SUMMARY: The Nuclear Regulatory Commission is amending 10 CFR 9.95, Specific Exemptions, to identify more properly the pertinent Systems of Records and to correct the names of two of the 15 Systems of Records which contain exempt records.

EFFECTIVE DATE: February 2, 1982.

FOR FURTHER INFORMATION CONTACT: J. M. Felton, Director, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 492-27211.

SUPPLEMENTARY INFORMATION: In order to update and clarify the information contained in 10 CFR 9.95, it is necessary to add the numerical designations for the NRC Systems of Records and to correct the names of two of the Systems of Records which contain exempt records. For purposes of convenience, the 15 exempted systems have been rearranged in numerical order.

Because these corrections and clarifications relate solely to minor procedural matters, good cause exists for omitting notice of proposed rulemaking and for making the amendments effective immediately upon publication without the customary 30-day notice.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552, 552a and 553 of Title 5 of the United States Code, as amended, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 9, are published as a document subject to codification.

47 FR 56314
Published 12/16/82
Effective 12/16/82

Nomenclature Changes To Implement Executive Order 12356

See Part 2 Statements of Consideration

49 FR 19623
Published 5/9/84
Effective 5/9/84

Information Collection Requirements; Display of OMB Control Numbers

See Part 0 Statements of Consideration

> 49 FR 30457
Published 7/31/84
Effective 7/31/84

10 CFR Part 9

Charges for the Production of Records

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations by revising the charges for copying records publicly available at the NRC Public Document Room in Washington, D.C. The amendments are necessary in order to reflect the change in copying charges resulting from the Commission's award of a new contract for the copying of records. In addition, the amendments would provide for any future change in copying charges to become immediately effective for the interim period pending completion of the Commission's rulemaking to establish the new charges.

EFFECTIVE DATE: July 31, 1984.

FOR FURTHER INFORMATION CONTACT: Francis X. Cameron, Office of the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: 301-492-8689.

SUPPLEMENTARY INFORMATION:

I. Background

The NRC maintains a Public Document Room (PDR) at its headquarters at 1717 H Street, NW, Washington, DC. The PDR contains an extensive collection of publicly available technical and administrative records that the NRC receives or generates. Requests by the public for the reproduction of records at the PDR have traditionally been accommodated by a copying service contractor selected by the NRC. The schedule of reproduction charges to the public established in the copying service contract is set forth in 10 CFR 9.14 of the Commission's regulations. Due to circumstances beyond the Commission's control, the present contract was abruptly terminated. As a result, the NRC has recently awarded a new copying service contract. On June 21, 1984, the Commission published proposed amendments to revise the fee schedule set forth in 10 CFR 9.14 (49 FR 25482). The proposed fee schedule reflects the changes in copying charges to the public that have resulted from the awarding of the new contract for the reproduction of records at the PDR.

In addition, § 9.14(a)(5) of the proposed amendments provided for any future change in copying charges to become immediately effective for the interim period pending completion of the Commission's rulemaking to establish the new fee schedule.

Finally, the proposed amendments deleted those provisions of § 9.14(a) that did not pertain to the price to be charged for the copying of records. Accordingly, the name and address of the current contractor in § 9.4(a)(3)(ii) and the billing information in § 9.14(a)(1)(v) and § 9.14(a)(3)(ii) were deleted.

II. Comments

Two comment letters were received on the proposed rule, both from the nuclear industry. One commenter was concerned exclusively with the quality of the performance of the new contractor and with the contractor's new billing procedures. Although these comments are outside of the scope of this rulemaking, the Commission would note that performance standards have been incorporated into the new contract and contractor performance will be evaluated in the course of the NRC's normal contract review process.

The second commenter recommended that the charges specified in § 9.14(a)(1) be *maximum* charges. Consequently, only *increases* in these maximum charges would need to be published as a proposed rule. According to this commenter, the suggested revisions would eliminate the need for proposed rulemaking when costs *decreased* and would lower the number of mail order requests which are subsequently cancelled due to the lack of notice of the increased charges. In response, the Commission believes that it is obligated to specify the exact charges for the reproduction of records, rather than simply a maximum price. Therefore, any change in the prices specified in § 9.14(a)(1) will necessitate the use of the requisite rulemaking procedures.

III. Final rule

The final rule would revise the fee schedule set forth in 10 CFR 9.14(a) to reflect the new prices for the copying of NRC records that have resulted from the awarding of the new contract for the reproduction of records at the PDR. In addition, § 9.14(a)(5) of the final rule provides for any future changes in copying charges to become immediately effective for the interim period pending completion of the Commission's rulemaking to establish the new fee schedule. This provision will ensure that the full reproduction cost will be borne by the person requesting the records, and will not require the NRC to subsidize reproduction costs during the interim period.

The final rule will also delete those provisions of § 9.14(a) that do not pertain to the price to be charged for the copying of records. Accordingly, the name and address of the current contractor in § 9.14(a)(3)(ii) and the billing information in § 9.14(a)(1)(v) and § 9.14(a)(3)(ii) have been deleted. In the future, this information will routinely be available from the PDR.

In addition to the above revisions, all of which were proposed in the Federal Register Notice of June 21, 1984, the NRC Staff has recommended that the charge specified in § 9.14(b)(1) for the copying of records at locations other than the PDR conform to the new charge specified in § 9.14(a)(1)(i) for the copying of records at the PDR. The charges specified in these two sections have traditionally been the same in order to afford equitable treatment to those persons with access to the PDR, and those who do not have access to the PDR. In order to maintain this policy, the final rule has revised § 9.14(b)(1) to specify a charge of seven cents per page.

The final rule will be immediately effective upon publication. The Commission believes that good cause exists under 5 U.S.C. 553(d)(3) to waive the usual 30-day delay in the effective date of a final rule. Users of the PDR were notified on May 22, 1984 that a new contract was being awarded and were notified on June 8, 1984 of the new contract prices. Therefore, users of the PDR had a reasonable opportunity to prepare for the revised fee schedule contained in this final rule. In addition, the NRC has been subsidizing the difference in cost between the old fee schedule and the new fee schedule, pending the effective date of the final rule. An immediate effective date will eliminate the unnecessary costs incurred through this continued subsidy and will place full reproduction costs on the person requesting the records.

Regulatory Flexibility Act

5 U.S.C. 552(a)(4)(A) requires the NRC, as a Federal agency, to promulgate regulations ". . . specifying a *uniform* schedule of fees applicable to all constitutent units of such agency." (emphasis added). Therefore, no analysis of any differential impacts on small entities is necessary.

Paperwork Reduction Act Statement

This final rule contains no information collection requirements and therefore is not subject to the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.).

List of Subjects in 10 CFR Part 9

Freedom of information, Penalty, Privacy, Reporting and recordkeeping requirements, Sunshine Act.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is adopting the following amendments to 10 CFR Part 9.

48 FR 31259
Published 8/6/84
Effective 8/6/84

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10 CFR Part 9

Charges for the Production of Records

Correction

In FR Doc. 84–20177, beginning on page 30457, in the issue of Tuesday, July 31, 1984, on page 30458, in the first column, in paragraph "1.", in the authority for Subpart A, in the second line, "31 U.S.C. 9710" should read "31 U.S.C. 9701".

➢ 50 FR 20889
Published 5/21/85
Effective on an interim
basis on 5/21/85

10 CFR Part 9

Government in the Sunshine Act Regulations

AGENCY: Nuclear Regulatory Commission.

ACTION: Interim rule with request for comments.

SUMMARY: The Nuclear Regulatory Commission is making an interim rule change to conform its definition of a "meeting" under the Government in the Sunshine Act (5 U.S.C. 552b) to the statutory intent, as clarified in the unanimous 1984 decision of the United States Supreme Court in *Federal Communications Commission* v. *ITT World Communications*, —— U.S. ——, 104 S.Ct. 1936. The Commission believes that this change would serve to effectuate the Congressional intent that background briefings and generalized discussions of agency business not be considered "meetings" for Sunshine Act purposes, and that adherence to statutory standards will help assure both fuller information for the Commissioners and greater collegiality in their performance of their duties. The rule change will be applied on an interim basis, pending submission and evaluation of comments and publication of a final rule.

EFFECTIVE DATE: The rule change will be effective on an interim basis on May 21, 1985. Comments on whether the interim rule change should be made final must be received on or before June 20, 1985. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

ADDRESSES: Interested persons are invited to send written comments or suggestions to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch. Comments may also be delivered to Room 1121, 1717 H Street, NW., Washington, D.C. between 8:15 a.m. and 5:00 p.m. Copies of any documents received may be examined at the NRC Public Document Room, 1717 H Street, NW., Washington, D.C. 20555.

FOR FURTHER INFORMATION CONTACT: Peter Crane, Office of General Counsel, United States Nuclear Regulatory Commission, Washington, DC 20555, telephone: 202–634–1465.

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SUPPLEMENTARY INFORMATION: The NRC's current Sunshine Act regulations (10 CFR § 9.100–109), define a "meeting" as follows, at 10 CFR § 9.101(c):

> "Meeting" means the deliberations of at least a quorum of Commissioners where such deliberations determine or result in the joint conduct or disposition of official business, but does not include deliberations required or permitted by §§ 9.105, 9.106, or 9.108(c),[1] gatherings of a social or ceremonial nature, or briefings of the Commission by representatives of other agencies or departments of the United States government, or representatives of foreign governments or international bodies where such briefings or discussions are informational in nature and

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[1] These three sections definition refer to procedures for implementing the Sunshine Act itself, and have no bearing on the Commission's conduct of its everyday duties under the Atomic Energy Act, Energy Reorganization Act, and other statutes.

> are not conducted with specific reference to any particular matter then pending before the Commission.

It will at once be noticed that the only type of briefing which is explicitly exempted from the definition of "meeting" is a briefing by a representative of another agency or department or a foreign or international body. Likewise, the only type of "gathering" of Commissioners which is expressly exempted from the definition is one of a "social or ceremonial nature." Thus under the NRC's regulations, the following types of meetings would all be subject to the Sunshine Act's meeting requirements: a general background briefing by the NRC staff on a technical issue common to a number of plants; informal discussion of problems likely to face the agency in the coming year; a discussion of the effectiveness of a particular office in meeting the Commission's needs; and a discussion of the state of relations between the Commission and its oversight committees, or with other government agencies. It is the Commission's view that the Supreme Court's 1984 decision in *FCC* v. *ITT World Communications*, —— U.S. ——, 104 S.Ct. 1936, strongly suggests that none of these topics necessarily falls within the class of discussions that triggers the "meeting" requirement of the Sunshine Act.

In 1984, the Supreme Court provided its first guidance on the Sunshine Act. *FCC* v. *ITT World Communications*, —— U.S. ——, 104 S.Ct. 1936, was decided by a unanimous Court on April 30, 1984. The case arose when three members of the FCC, constituting a quorum of the agency's Telecommunications Committee (a subdivision to which decisionmaking power had been delegated) traveled to Europe to take part in an international conference of telecommunications regulators. An American company, aware that the FCC Commissioners planned to use the conference to argue for increased competition in the provision of telecommunications services, filed suit in District Court, charging among other things that the presence of a sufficient number of Commissioners to decide agency business rendered the international conference a Commission "meeting" under the Sunshine Act, and that the meeting was required to be held in the open. The District Court ruled for the company, as did the D.C. Circuit Court of Appeals, in a decision written by Judge Bazelon.

The Supreme Court, in a 9–0 decision written by Justice Powell, reversed the D.C. Circuit's holding. Its discussion of the meaning of "meeting" under the Sunshine Act is worth quoting at some length.

> Congress in drafting the Act's definition of "meeting" recognized that the administrative process cannot be conducted entirely in the public eye. "[I]nformal background discussions [that] clarify issues and expose varying views" are a necessary part of an agency's work. See S. Rep. No. 94–354, at 19 (1975). The Act's procedural requirements effectively would prevent such discussions and thereby impair normal agency operations without achieving significant public benefit. Section 552b(a)(2) therefore limits the Act's application to meetings "where at least a quorum of the agency's members . . . conduct or dispose of official agency business." S. Rep. No. 94–354, at 2.

In a footnote, the Court reviewed the pertinent legislative history:

> The evolution of the statutory language reflects the congressional intent precisely to define the limited scope of the statute's requirements. See generally, H.R. Rep. No. 94–880, Part 2, at 14 (1976). For example, the Senate substituted the term "deliberations" for the previously proposed terms—"assembly or simultaneous communication," H.R. 11656, 94th Cong., 2d Sess. § 552b(a)(2) or "gathering, S. 5, 94th Cong., 1st Sess. § 201(a) (1976)—in order to "exclude many discussions which are informal in nature." S. Rep. 94–354, at 10; see *id.*, at 18. Similarly, earlier versions of the Act had applied to any agency discussions that "concern[ ] the joint conduct or disposition of agency business." H.R. 11656, *supra*, § 552b(a)(2). The Act now applies only to deliberations that "determine or result in" the conduct of "official agency business." The intent of the revision clearly was to permit preliminary discussion among agency members. See 122 Cong. Rec. 28474 (1976) (remarks of Rep. Fascell).

The Court then explained that though the FCC's Telecommunications Committee was subject to the Sunshine Act (since it could act on behalf of the agency, under a delegation of authority from the Commission as a whole), it did not appear that the Committee had, by participating in the international conference, engaged in "deliberations [that] determine or result in the joint conduct or disposition of official agency business." The Court offered a definition of this by no means self-explanatory language:

> This statutory language contemplates discussions that "effectively predetermine official actions." See S. Rep. No. 95–354, at 19; accord *id.*, at 18. Such discussions must be "sufficiently focused on discrete proposals or issues as to cause or be likely to cause the individual participating member to form reasonably firm positions regarding matters pending or likely to arise before the agency." R. Berg and S. Klitzman, An Interpretive Guide to the Government in the Sunshine Act 9 (1978) (hereinafter Interpretive Guide).

The Court noted that ITT had not alleged that the Conference sessions included formal action on applications before the FCC, nor that the sessions "resulted in firm positions on particular matters pending or likely to arise before the Committee." Rather, the conference sessions "provided general background information to the Commissioners and permitted them to engage with their foreign counterparts in an exchange of views by which decisions already reached by the Commission could be implemented." The Court added: "As we have noted, Congress did not intend the Sunshine Act to encompass such discussions."

The Court observed that the D.C. Circuit had not found that the FCC Commissioners at the conference were actually deliberating on matters within their formally delegated authority; rather, the lower court had inferred an authority, not formally delegated, to engage in discussions on behalf of the Commission. The lower court "then concluded that these discussions were deliberations that resulted in the conduct of official agency business, as the discussions 'play[ed] an integral role in the Commission's policy-making processes.' [citation omitted]"

The Court categorically rejected the Court of Appeals' reasoning:

> We view the act differently. * * * Under the reasoning of the Court of Appeals, any group of members who exchange views or gathered information on agency business apparently could be viewed as a "subdivision * * * authorized to act on behalf of the agency." * * * Moreover, the more expansive view of the term "subdivision" adopted by the Court of Appeals would require public attendance at a host of informal conversations of the type Congress understood to be necessary for the effective conduct of agency business.

The interim rule incorporates verbatim the Supreme Court's language in the *ITT* decision. The exceptions for "social and ceremonial" gatherings and for informational briefings by other agencies or international organizations are dropped, since under the proposed rule they would be redundant. The Commission believes, based on almost eight years of operation under the current rules, that a decision to conform its regulations to the literal requirements of the statute as interpreted by the Supreme Court will improve its ability to do the public's business. The ability to hold informal preliminary briefings can help assure that Commissioners are well informed about subject areas well before any particularized proposal reaches them for consideration. The ability to hold free-flowing discussions of a variety of problems likely to face the agency, or to get together for "brainstorming sessions," can foster both collegiality and sound management. It is through such generalized background discussions that Commissioners can decide what topics should become the subject of more particularized proposals, discussions of which would fall within the Act's definition of "meeting."

In so changing its rules, the Commission would in no sense be seeking to evade the Sunshine Act's requirements. Rather, it would be giving belated recognition to the fact—understood by the Congress and reaffirmed by the Supreme Court—that some types of informal discussions, necessary for sound agency functioning, do not belong within the purview of the Sunshine Act.

II

In one other respect, the Commission placed on itself a restriction that other agencies did not see fit to adopt. The NRC's rules provide that when a meeting is closed, one of the following two alternatives must be adopted: either, (1) The Comission itself, as the last item if business in the meeting, reviews the course of the meeting and decides which portions of the transcript or recording can be withheld, or (2) the Secretary, "upon the advice of the Office of General Counsel and after consulting with the Commission, shall make such determinations." These rules apply whether or not anyone has evinced any interest in learning the nature of the Commission's discussions.

Other agencies have taken the common-sense view that they will review the transcripts if and when someone asks for them. The Federal Communications Commission, in promulgating its Sunshine Act regulations in 1977, dismissed the suggestion that every transcript of every closed meeting should be reviewed as a matter of course (and later re-reviewed if any portions continued to be withheld). The FCC said:

> We reject the proposition that the transcript of each closed meeting should be reviewed regularly to determine whether it can be made available to the public. The proposition is impracticable. * * * Many of the matters acted on by the Commission in closed meetings should be of little or no interest to the general public and should rarely be made the subject of requests for transcripts. A periodic review of such transcripts would be a waste of time and public funds. Transcripts may be placed in the public file just after the meeting is held, but otherwise will be reviewed only when requests for copies are received. 42 Fed. Reg. 12867 (March 7, 1977).

In addition, in the interest of the efficient use of resources, the Commission is amending its rules to clarify that Sunshine Act recordings, transcripts, and minutes of closed Commission meetings will be reviewed for "closability" only when a request is received. The Commission agrees with the position taken in this regard by the Federal Communications Commission, which likewise found that it would be a waste of public funds to review transcripts in which no one has evinced any interest. Moreover, since the Commission's present rules require the Commissioners themselves to be consulted on these reviews, the present rule is an unnecessary burden on the time of the Commissioners. As revised, the relevant subsection provides that the review will take place if requested within the period during which the recording, transcript, or minutes must be retained. The provision for review by the Commissioners at the end of the meeting itself is dropped from the rule, as this provision is impracticable and is not currently used.

While the Commission is seeking public comment on the rule change, it has decided to make the rule effective on publication on an interim basis pending submission and evaluation of comments, and publication of a final rule. It is authorized to do so because the change to 10 CFR § 9.101(c) is both an interpretative rule and a rule of agency procedure, and the changes to 10 CFR § 9.108(c) is a rule of agency procedure. Such rule changes are exempt from proposed rulemaking and deferred effectiveness under 5 U.S.C. § 553 of the Administrative Procedure Act. The change to 10 CFR § 9.101(c) is interpretative because it merely specifies the Commission's interpretation of the term "meeting" in the Sunshine Act. *Batterton* v. *Marshall*, 648 F.2d 694, 705 (D.C. Cir. 1980). The changes to 10 CFR 9.101(c) and 10 CFR 9.108(c) are rules of agency procedure because they govern how the Commission conducts its business and do not in any way alter the substantive rights or interests of persons affected by Commission action. *Batterton* v. *Marshall, supra* at 707.

Making the rule change effective on an interim basis will not only improve the conduct of Commission business in the interim by facilitating the flow of information to the Commission and fostering collegiality, but will also enable the Commission to gain some limited experience with the rule change before making any decision on the final rule. However, in this interim period the Commission will *not* be using the new definition of meeting to permit private Commission discussions in any briefings or other Commission sessions devoted to specific initial licensing cases or the TMI–1 restart case. In this interim period initial licensing and TMI–1 restart will, as matter of policy, be governed by the "old" expansive definition of "meeting".

Environmental Impact—Categorical Exclusion

The amendments amend the Commission's rules relating to the Sunshine Act codified in 10 CFR Part 9 and therefore meet the eligibility criteria for the categorical exclusion set forth in 10 CFR 51.22(c)(1). Accordingly, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared in connection with the issuance of the amendments.

Paperwork Reduction Act Statement

The rule contains no information collection requirements and therefore is not subject to the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. §§ 3501 et seq.).

List of Subjects in 10 CFR Part 9

Freedom of information, Penalty, Privacy, Reporting and recordkeeping requirements, Sunshine Act.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is adopting the following amendments to 10 CFR Part 9 on an interim basis. As noted, public comment is solicited as to whether they should be made final.

Separate Statement of Chairman Palladino—Sunshine Act Rulemaking

I fully support the proposal set forth in this notice of rulemaking to change the Commission's Sunshine Act rules. However, I disagree with the policy decision to use the revised definition of a "meeting" during the interim period during which public comments are received and a final rule is published.

I doubt the usefulness of such interim application. If, on the one hand, the Commission applies the new definition narrowly—that is, if it exempts from the definition of "meeting" only the clearest of cases—then it will not gain much of value from interim application. If, on the other hand, the Commission applies the new definition broadly, then it risks potentially counter-productive consequences for its overall objective to conform its rules to the Sunshine Act.

Separate Views of Commissioner Asselstine

I approved publication of the proposed changes to our rule implementing the Sunshine Act only in order to obtain comment on those changes. However, I have significant concerns about the difficulty of administering the proposed standard which make it impossible for me to endorse the proposed rule. I particularly invite comment on the concerns expressed below.

The Sunshine Act is not an easy act to interpret or to apply. This is the primary reason the Commission's present regulation was written as it was. The Commission's regulation sets up a bright line for determining what constitutes a meeting and what does not. While the Commission may have given up some flexibility when it set up that bright line standard, it did so with a reason. A standard which provided more flexibility would, of necessity, have been less certain and would have created problems of interpretation. Adopting a more flexible standard would have made it easier for the Commission to misapply the Act inadvertently in a particular case.

The standard in the proposed rule suffers from just these problems. Because the standard is vague and subjective, it will be much more difficult to administer than the present standard. Predicting whether a particular meeting will consist of discussions "sufficiently focused on discrete proposals or issues as to cause or be likely to cause the individual participating members to form reasonably firm positions regarding matters pending or likely to arise before the agency" will require nothing short of divination. And, if the Commission guesses wrong, there is no remedy because if there is no "meeting" there will be no notice, no transcript, and no minutes.

If the Commission insists on going forward with the proposed rule, it should a least have made clear in the statement of considerations what change to present practice the rule is intended to effect. The Commission should have explained, with concrete examples, exactly what kind of meetings now held by the Commission will be treated as "gatherings" under the proposed rule. Or, if the intent is to create a new type of meeting not now held by the Commission, that should have been made clear.

I also cannot support the Commission's decision to make this rule immediately effective by applying it while the comment period runs. A rule changing the manner in which the Commission implements the Government in the Sunshine Act, an act the purpose of which was to provide the public with "the fullest practicable information regarding the decisionmaking processes of the Federal Government" (P.L. No. 94–409 § 2), is clearly a rule in which the public has an interest. The Commission should await public comment before putting the rule into effect. The Commission has operated under its present rule for eight years without catastrophe. Waiting thirty more days for public comment hardly seems to be an onerous burden.

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50 FR 25204
Published 6/18/85
Effective 6/18/85

10 CFR Part 9

Charges for the Production of Records

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations by revising the charges for copying records publicly available at the NRC Public Document Room in Washington, DC. The amendments are necessary in order to reflect the change in copying charges resulting from the Commission's award of a new contract for the copying of records.

EFFECTIVE DATE: June 18, 1985.

FOR FURTHER INFORMATION CONTACT: John Philips, Chief, Rules and Procedures Branch, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: 301–492–7086.

SUPPLEMENTARY INFORMATION: The NRC maintains a Public Document Room (PDR) at its headquarters at 1717 H Street, NW, Washington, DC. The PDR contains an extensive collection of publicly available technical and administrative records that the NRC receives or generates. Requests by the public for the reproduction of records at the PDR have traditionally been accommodated by a copying service contractor selected by the NRC. The schedule of reproduction charges to the public established in the copying service contract is set forth in 10 CFR 9.14 of the Commission's regulations. The NRC has recently awarded a new copying service contract. The revised fee schedule reflects the changes in copying charges to the public that have resulted from the awarding of the new contract for the reproduction of records at the PDR.

Because these are amendments dealing with agency practice and procedures, the notice provisions of the Administrative Procedure Act do not apply pursuant to 5 U.S.C. 553(b)(A). In addition, the PDR users were notified on June 3, 1985, that the new contract was being awarded and that the new prices would go into effect on June 10, 1985. The amendments are effective upon publication in the **Federal Register.** Good cause exists to dispense the usual 30-day delay in the effective date because the amendments are of a minor and administrative nature dealing with agency procedures.

Regulatory Flexibility Act

5 U.S.C. 552(a)(4)(A) requires the NRC, as a Federal agency, to promulgate regulations ". . . specifying a *uniform* schedule of fees applicable to all constitutent units of such agency." (emphasis added). Therefore, no analysis of any differential impacts on small entities is necessary.

Paperwork Reduction Act Statement

This final rule contains no information collection requirements and therefore in not subject to the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.).

List of Subjects in 10 CFR Part 9

Freedom of information, Penalty, Privacy, Reporting and recordkeeping requirements, Sunshine Act.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is adopting the following amendments to 10 CFR Part 9.

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50 FR 25907
Published 6/24/85
Extended comment period expires 7/24/85

10 CFR Part 9

Government in the Sunshine Act Regulations

AGENCY: Nuclear Regulatory Commission.

ACTION: Interim rule with request for comments: Extension of comment period.

SUMMARY: On May 21, 1985 (50 FR 20889), the Nuclear Regulatory Commission published an interim rule change conforming the definition of "meeting" in its Government in the Sunshine Act regulations to guidance contained in a recent Supreme Court decision. The notice provided a 30-day period for public comment on whether the interim rule change should be made final. Two interested parties having requested a two-week extension of time, based on the significance of the issues involved and other factors, the NRC has

decided to extend the comment period by 15 days to July 5, 1985.

DATE: The extended comment period expires July 5, 1985. Comments received after that date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before that date.

ADDRESSES: Submit written comments to the Secretary of the Commission, Washington, D.C. 20555, attention: Docketing and Servicing Branch. Copies of comments received may be examined at the NRC Public Document Room, 1717 H Street, NW., Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Peter Crane, Office of General Counsel, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone (202) 634-1465.

Dated at Washington, D.C. this 19th day of June, 1985.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,
Secretary of the Commission.

50 FR 27214
Published 7/2/85
Effective 7/1/85

10 CFR Part 9

Public Records; Freedom of Information Act; Granting Appeals

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission revises one section of its Freedom of Information Act (FOIA) regulations to provide that appeals from initial denials of requests for information under the FOIA shall be decided by the Secretary of the Commission, with the advice and concurrence of the Office of General Counsel, instead of being decided by the Commission. The Secretary will be required to consult with the Commission before granting an appeal.

EFFECTIVE DATE: July 1, 1985.

FOR FURTHER INFORMATION CONTACT: Theresa Hajost, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (202) 634-1493.

SUPPLEMENTARY INFORMATION: Under the Commission's current FOIA regulations (10 CFR 9.15), appeals from initial denials of requests for documents under the FOIA (5 U.S.C. 552) made by committees, boards, panels, and offices reporting to the Commission are addressed to the Commission. Under section 161(n) of the Atomic Energy Act of 1954, as amended, 42 U.S.C. 2201(n), the Commission has the power to delegate functions such as this to "other officers of the Commission."

The Commission is delegating the FOIA appeal function to the Secretary of the Commission. The Secretary will exercise this authority only with the advice and concurrence of the Office of the General Counsel. The Secretary will consult with the Commission when granting an appeal. When denying an appeal, the Secretary will consult with the Commission as appropriate. Decisions of the Secretary on appeals shall constitute final agency action.

Appeals currently pending before the Commission will be referred to the Secretary.

Because this is a rule of procedure and practice, the Commission finds, pursuant to 5 U.S.C. 553(b)(A), that advance notice and opportunity to comment are not required. Accordingly, the Commission finds that because these amendments relate solely to matters of agency organization, procedure, or practice, good cause exists for omitting notice of proposed rulemaking and public procedure thereon, as unnecessary, and for making the amendments effective upon publication in the **Federal Register.** Because this revision is not a final rule requiring notice of proposed rulemaking, under 5 U.S.C. 553, the provision of 5 U.S.C. 603 requiring a regulatory flexibility analysis does not apply.

Environmental Impact: Categorical Exclusion

The NRC has determined that this final rule is the type of action described in categorical exclusion 10 CFR 51.22(c)(1). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this final rule.

Paperwork Reduction Act Statement

This final rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501, *et seq.*).

List of Subjects in 10 CFR Part 9

Freedom of information, Penalty, Privacy, Reporting and recordkeeping requirements, Sunshine Act.

For the reasons set out in the preamble and under authority of the Atomic Energy Act of 1954, as amended, and 5 U.S.C. 553, the NRC is adopting the following amendments to 10 CFR Part 9.

PART 10

CRITERIA AND PROCEDURES FOR DETERMINING ELIGIBILITY FOR ACCESS TO RESTRICTED DATA OR NATIONAL SECURITY INFORMATION OR AN EMPLOYMENT CLEARANCE

Subpart A—General Provisions

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10.1 Purpose.
10.2 Scope.
10.3 [Reserved]
10.4 Policy
10.5 Definitions.

Subpart B—Criteria for Determining Eligibility for Access to Restricted Data or National Security Information or an Employment Clearance

10.10 Application of the criteria.
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10.21 Suspension of access authorization and/or employment clearance.
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10.25 NRC Hearing Counsel.
10.26 Appointment of Hearing Examiner.
10.27 Prehearing proceedings.
10.28 Conduct of hearing.
10.29 Recommendation of the Hearing Examiner.
10.30 New evidence.
10.31 Actions on the recommendations.
10.32 Recommendation of the NRC Personnel Security Review Examiners.
10.33 Action by the Executive Director for Operations.
10.34 Action by the Commission.
10.35 Reconsideration of cases.

Subpart D—Miscellaneous

10.36 Terminations.
10.37 Attorney representation.
10.38 Certifications.

Authority: Sec. 145, 68 Stat. 942, as amended; 42 U.S.C. 2165; sec. 161, 68 Stat. 948, as amended; 42 U.S.C. 2201, sec. 201(f) 88 Stat. 1243, 42 U.S.C. 5841; E.O. 10450, 3 CFR 1949-1953 comp., p. 936, as amended; E.O. 10865, 3 CFR 1959-1963 comp., p. 398, as amended, 3 CFR, Chap. IV.

Subpart A—General Provisions

§ 10.1 Purpose.

This part establishes the criteria, procedures, and methods for resolving questions concerning: (a) The eligibility of individuals who are employed by or applicants for employment with NRC contractors, agents, and licensees of the NRC, individuals who are NRC employees or applicants for NRC employment, and other persons designated by the Executive Director for Operations of the NRC, for access to Restricted Data pursuant to the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, or for access to national security information ; and (b) the eligibility of NRC employees, or the eligibility of applicants for employment with the NRC, for employment clearance. This part is published to implement such Statutes and Executive Orders 10865, 25 FR 1583 (February 24, 1960), and 10450, 18 FR 2489 (April 27, 1954).

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§ 10.2 Scope.

The criteria and procedures in this part shall be used in determining eligibility for NRC access authorization and/or employment clearance involving:

(a) Employees (including consultants) of contractors and agents of the Nuclear Regulatory Commission and applicants for employment;

(b) Licensees of the NRC and their employees (including consultants) and applicants for employment; and

(c) NRC employees (including consultants) and applicants for employment;

(d) Any other person designated by the Executive Director for Operations of the Nuclear Regulatory Commission.

§ 10.3 [Reserved]

§ 10.4 Policy.

It is the policy of the Nuclear Regulatory Commission to carry out its responsibility for the security of the nuclear energy program in a manner consistent with traditional American concepts of justice. To this end, the Commission has established criteria for determining eligibility for access authorization and/or employment clearance and will afford those individuals described in § 10.2 the opportunity for administrative review of questions concerning their eligibility for access authorization and/or employment clearance.

§ 10.5 Definitions.

As used in this part:

(a) "Access authorization" means an administrative determination that an individual (including a consultant) who is employed by or an applicant for employment with the NRC, NRC contractors, agents, and licensees of the NRC, or other person designated by the Executive Director for Operations, is eligible for a security clearance for access to Restricted Data or national security information.

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(b) "Hearing Examiner" means a qualified attorney appointed by the Director, Office of Administration, to conduct a hearing in accordance with this part.

(c) "Hearing Counsel" means an NRC attorney assigned by the Executive Legal Director to prepare and administer hearings in accordance with this part.

(d) "Personnel Security Review Examiners" are persons designated by the Executive Director for Operations to conduct a review of the record in accordance with this part.

(e) "Commission" means the Nuclear Regulatory Commission of five members or a quorum thereof sitting as a body, as provided by Section 201 of the Energy Reorganization Act of 1974, or its designee.

(f) "Employment Clearance" means an administrative determination that an individual (including a consultant) who is an NRC employee or applicant for NRC employment and other persons designated by the Executive Director for Operations of the NRC is eligible for employment or continued employment pursuant to subsection 145 b. of the Atomic Energy Act of 1954, as amended.

(g) "Eligible" or "Eligibility" means both initial eligibility and continued eligibility of an individual for access authorization and/or employment clearance.

(h) "National Security Information" means information that is owned by, produced for or by, or under the control of the United States Government, and that has been determined, pursuant to Executive Order 12356 or antecedent orders, to require protection against unauthorized disclosure, and is so designated.

(i) "Restricted Data" means all data concerning design, manufacture, or utilization of atomic weapons, the production of special nuclear material, or the use of special nuclear material in the production of energy, but shall not include data declassified or removed from the Restricted Data category pursuant to Section 142 of the Atomic Energy Act of 1954, as amended.

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Subpart B—Criteria for Determining Eligibility for Access to Restricted Data or National Security Information or an Employment Clearance

§ 10.10 Application of the criteria.

(a) The decision as to access authorization and/or employment clearance is a comprehensive, common-sense judgment, made after consideration of all the information, favorable or unfavorable, relevant to whether the granting of access authorization and/or employment clearance would not endanger the common defense and security and would be clearly consistent with the national interest.

(b) The criteria in § 10.11 set forth a number of the types of derogatory information used to assist in making determinations of eligibility for access authorization and/or employment clearance. These criteria are not exhaustive but contain the principal types of derogatory information which create a question as to the individual's eligibility for access authorization and/or employment clearance. While there must necessarily be adherence to such criteria, the NRC is not limited to them, nor precluded from exercising its judgment that information or facts in a case under its cognizance are derogatory although at variance with, or outside the scope of, the stated categories. These criteria are subject to continuing review and may be revised from time to time as experience and circumstances may make desirable.

(c) When the reports of investigation of an individual contain information reasonably tending to establish the truth of one or more of the items in the criteria, such information shall be regarded as derogatory and shall create a question as to the individual's eligibility for access authorization and/or employment clearance. A question concerning the eligibility of an individual for access authorization and/or employment clearance shall be resolved in accordance with the procedures set forth in § 10.20 *et seq.*

(d) In resolving a question concerning the eligibility or continued eligibility of an individual for access authorization and/or employment clearance, the following principles shall be applied by the Director, Division of Security, Hearing Examiners, and Personnel Security Review Examiners:

(1) Information reasonably tending to establish the truth of one or more of the items in the criteria shall be the basis for recommending denial or revocation of access authorization and/or employment clearance unless evidence to support faith in the individual's reliability and trust-worthiness is affirmatively shown.

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(2) When deemed material to the deliberations, the extent of the activity, conduct, or condition, the period in which they occurred or existed, the length of time which has since elapsed, and the attitude and convictions of the individual shall be considered in determining whether the recommendation will be adverse or favorable.

§ 10.11 Criteria.

(a) The criteria for determining eligibility for access authorization and/or employment clearance shall relate, but not be limited, to the following where an individual:

(1) Committed, attempted to commit, aided, or abetted another who committed or attempted to commit any act of sabotage, espionage, treason, sedition, or terrorism.

(2) Publicly or privately advocated actions that may be inimical to the interest of the United States, or publicly or privately advocated the use of force or violence to overthrow the Government of the United States or the alteration of the form of government of the United States by unconstitutional means.

(3) Knowingly established or continued a sympathetic association with a saboteur, spy, traitor, seditionist, anarchist, terrorist, or revolutionist, or with an espionage agent or other secret agent or representative of a foreign nation whose interests may be inimical to the interests of the United States, or with any person who advocates the use of force or violence to overthrow the Government of the United States or the alteration of the form of government of the United States by unconstitutional means.

(4) Joined or engaged in any activity knowingly in sympathy with or in support of any foreign or domestic organization, association, movement, group, or combination of persons which unlawfully advocates or practices the commission of acts of force or violence to prevent others from exercising their rights under the Constitution or laws of the United States or any State or any subdivisions thereof by unlawful means, or which advocate the use of force and violence to overthrow the Government of the United States or the alteration of the form of government of the United States by unconstitutional means. (Ordinarily, criteria (3) and (4) will not include chance or casual meetings or contacts limited to normal business or official relations.)

(5) Deliberately misrepresented, falsified or omitted relevant and material facts from or in a personnel security questionnaire, a personal qualifications statement, a personnel security interview, or any other information submitted pursuant this part.

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(6) Willfully violated or disregarded security regulations or was grossly negligent with respect thereto to a degree which could endanger the common defense and security; or by intention or gross carelessness disclosed Restricted Data or national security information to any person not authorized to receive it.

(7) Has any illness or mental condition which in the opinion of competent medical authority may cause significant defect in the judgment or reliability of the individual.

(8) Has been convicted of crimes indicating habitual criminal tendencies.

(9) Has been convicted of a crime, or has a background, where the facts, circumstances, or conduct are of a nature indicating poor judgment, unreliabilty, or untrustworthiness.

(10) Is a user of alcohol habitually and to excess, or has been such without adequate evidence of rehabilitation.

(11) Has been, or is, a user of a drug or other substance listed in the schedules of Controlled Substances established pursuant to the Controlled Substances Act of 1970 (such as amphetamines,

barbiturates, narcotics, etc.), except as prescribed or administered by a physician licensed to dispense drugs in the practice of medicine, without adequate evidence of rehabilitation.

(12) Refused, without satisfactory explanation, to answer questions before a congressional committee, Federal or state court, or Federal administrative body including the NRC regarding charges relevant to the individual's eligibility for access authorization and/or employment clearance.

(13) Engaged in any other conduct or is subject to any other circumstances which tend to show that the individual is not reliable or trustworthy, or which furnishes reason to believe that the individual may be subject to coercion, influence, or pressures which may cause the individual to act contrary to the national interest.

§ 10.12 Interview and other investigation.

(a) The Director, Division of Security, Office of Administration, may authorize the granting of access authorization and/or employment clearance on the basis of the information in the possession of the NRC or may authorize the conduct of an interview with the individual, if the individual consents to be interviewed, or such other investigation as the Director deems appropriate. On the basis of such interview and/or investigation, the Director may authorize the granting of access authorization and/or employment clearance.

(b) The individual may elect on constitutional or other grounds not to participate in an interview or other investigation; however, such refusal or failure to furnish or authorize the furnishing of relevant and material information is deemed to be derogatory information pursuant to § 10.11(a)(5) and (12).

(c) If the director, Division of Security, cannot make a favorable finding regarding the eligibility of an individual for access authorization and/or employment clearance, the question of the individual's eligibility shall be resolved in accordance with the procedures set forth in § 10.20 *et seq.*

Subpart C—Procedures

§ 10.20 Purpose of the procedures.

These procedures establish methods for the conduct of hearings and administrative review of questions concerning an individual's eligibility for access authorization and/or employment clearance pursuant to the Atomic Energy Act of 1954, as amended, and Executive Orders 10450 and 10865, when a resolution favorable to the individual cannot be made on the basis of the interview or other investigation.

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§ 10.21 Suspension of access authorization and/or employment clearance.

In those cases where information is received which raises a question concerning the continued eligibility of an individual for access authorization and/or employment clearance, the Director, Division of Security, through the Director, Office of Administration, shall forward to the Executive Director for Operations, his or her recommendation as to whether the individual's access authorization and/or employment clearance should be suspended pending the final determination resulting from the operation of the procedures provided in this part. In making this recommendation the Director, Division of Security, shall consider such factors as the seriousness of the derogatory information developed, the degree of access of the individual to classified information, and the individual's opportunity by reason of his or her position to commit acts adversely affecting the national security. An individual's access authorization and/or employment clearance shall not be suspended except by the direction of the Executive Director for Operations.

§ 10.22 Notice to individual.

A notification letter, prepared by the Division of Security, approved by the Office of the Executive Legal Director, and signed by the Director, Office of Administration, shall be presented to each individual whose eligibility for access authorization and/or employment clearance is in question. Where practicable, such letter shall be presented to the individual in person. The letter will be accompanied by a copy of this part and shall state:

(a) That reliable information in the possession of the NRC has created a substantial doubt concerning the individual's eligibility for access authorization and/or employment clearance;

(b) The information that creates a substantial doubt regarding the individual's eligibility for access authorization and/or employment clearance, which shall be as comprehensive and detailed as the national security permits;

(c) That unless the individual files with the Director, Office of Administration, a written request for a hearing within 20 days of the individual's receipt of the notification letter, the Director, Division of Security, through the Director, Office of Administration, will submit a recommendation as to the final action to the Executive Director for Operations on the basis of the information in the possession of the NRC;

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(d) That if the individual files a written request for a hearing with the Director, Office of Administration, the individual must file with that request a written answer under oath or affirmation which admits or denies specifically each allegation and each supporting fact contained in the notification letter. A general denial is not sufficient to controvert a specific allegation. If the individual is without knowledge, he or she shall so state and that statement shall operate as a denial. The answer shall also state any additional facts and information that the individual desires to have considered in explanation or mitigation of allegations in the notification letter. Failure to specifically deny or explain or deny knowledge of any allegation or supporting fact shall be deemed an admission that the allegation or fact is true;

(e) That if the individual does not want to exercise his or her right to a hearing, but does want to submit an answer to the allegations in the notification letter, the individual may do so by filing with the Director, Office of Administration, within 20 days of his receipt of the notification letter, a written answer in accordance with the requirements of paragraph (d) of this section;

(f) That the procedures in § 10.24 *et seq.* shall apply to any hearing and review.

§ 10.23 Failure of individual to request a hearing.

(a) In the event the individual fails to file a written request for a hearing pursuant to § 10.22 within 20 days of his receipt of the notification letter, a recommendation as to the final action to be taken shall be made by the Director, Division of Security, through the Director, Office of Administration, to the Executive Director for Operations on the basis of the information in the possession of the NRC, including any answer filed by the individual.

(b) The Director, Office of Administration, may for good cause shown, at the request of the individual, extend the time for filing a written request for a hearing or for filing a written answer to the matters contained in the notification letter.

§ 10.24 Procedures for hearing and review.

(a) Upon receipt of a timely filed request for a hearing and answer complying with the requirements set forth in § 10.22, the Director, Office of Administration, shall forthwith appoint a Hearing Examiner, and Executive Legal Director shall forthwith assign an NRC attorney to act as Hearing Counsel. The Director, Office of Administration,

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shall promptly notify the individual of the identity of the Hearing Examiner and proposed hearing date, which shall be selected with due regard for the convenience of the parties and their representatives.

(b) Within 72 hours of being notified of the identity of the Hearing Examiner, the individual may request that the Hearing Examiner be disqualified for cause by filing with the Director, Office of Administration, a written statement of the individual's reasons for seeking disqualification. The time for filing the request may be extended by the Director, Office of Administration, for good cause shown. If the Director, Office of Administration, grants the request the procedures of paragraph (a) of this section and this paragraph shall be followed just as though there had been no prior appointment.

(c) The individual shall have the right to appear at the hearing before the Hearing Examiner, to be represented by counsel or other representative, to introduce documentary or other evidence, and to call, examine, and cross-examine witnesses, subject to the provisions and limitations set forth in this part.

§ 10.25 NRC Hearing Counsel.

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(a) Hearing Counsel assigned pursuant to § 10.24 shall, prior to the scheduling of the hearing, review the information in the case and shall request the presence of witnesses and the production of documents and other physical evidence relied upon the Director, Division of Security, in making his or her finding that a question exists regarding the eligibility of the individual for NRC access authorization and/or employment clearance in accordance with the provisions of this part. When the presence of a witness and the production of documents and other physical evidence is deemed by the Hearing Counsel to be necessary or desirable for a determination of the issues, the Director, Division of Security, shall make arrangements for the production of such evidence and for such witnesses to appear at the hearing by subpoena or otherwise.

(b) Hearing Counsel is authorized to consult directly with individual's counsel or representative or the individual, if the individual is not so represented, for purposes of reaching mutual agreement upon arrangements for expeditious hearing of the case. Such arrangements may include clarification of issues and stipulations with respect to testimony and contents of documents and other physical evidence. Such stipulations when entered into shall be binding upon the individual and the NRC for the purposes of this part. Prior to any consultation with the individual, the Hearing Counsel shall advise the individual of his or her rights under this part, of his or her right to counsel or other representation, and of the possibility that any statement made by the individual to the Hearing Counsel may be used in subsequent proceedings.

(c) The individual is responsible for producing witnesses in his or her own behalf and/or presenting other evidence before the Hearing Examiner to support the individual's answer and defense to the allegations contained in the notification letter. When requested, however, Hearing Counsel shall assist the individual to the extent practicable and necessary. The Hearing Counsel may at his or her discretion request the Director, Division of Security, to arrange for the issuance of subpoenas for witnesses to attend the hearing in the individual's behalf, or for the production of specific documents or other physical evidence, provided a showing of the necessity for such assistance has been made.

§ 10.26 Appointment of Hearing Examiner.

The appointment of a Hearing Examiner, pursuant to § 10.24 of this part, shall be from a list of qualified attorneys possessing the highest degree of integrity, ability, and good judgment. To qualify, an attorney shall have an NRC "Q" access authorization and may be an employee of the NRC, its contractors, agents or licensees. However, no employee or consultant of the NRC shall serve as Hearing Examiner hearing the case of an employee (including a consultant) or applicant for employment with the NRC; nor shall any employee or consultant of an NRC contractor, agent or licensee serve as Hearing Examiner hearing the case of an employee (including a consultant) or an applicant for employment of that contractor, agent, or licensee. No Hearing Examiner shall be selected who has knowledge of the case or of any information relevant to the disposition of it, or who for any reason would be unable to issue a fair and unbiased recommendation.

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§ 10.27 Prehearing proceedings.

(a) After the appointment of the Hearing Examiner, he or she shall be furnished the record in the case, which shall consist of the letter of notification, the request for hearing and its supporting answer, and the notice of hearing, if it has been issued, and any stipulations agreed to by the individual and the Hearing Counsel.

(b) The Hearing Examiner may on his or her own motion, or on that of either party, convene a prehearing conference with the Hearing Counsel and the individual and his or her counsel or representative, if any, for the purpose of clarifying the issues, identifying witnesses who may be called, identifying documents and other physical evidence that may be offered into evidence, and entering into stipulations of fact.

(c) The parties will be notified by the Hearing Examiner at least ten days in advance of the hearing of the time and place of the hearing. For good cause shown, the Hearing Examiner may order postponements or continuances from time to time. If, after due notice, the individual fails to appear at the hearing, or appears but is not prepared to proceed, the Hearing Examiner shall, unless good cause is shown, return the case to the Director, Division of Security, who shall make a recommendation on final action to be taken, through the Director, Office of Administration, to the Executive Director for Operations on the basis of the information in the possession of the NRC.

§ 10.28 Conduct of hearing.

(a) The Hearing Examiner shall conduct the hearing in an orderly, impartial and decorous manner. Technical rules of evidence may be relaxed so that a full evidentiary record may be made based on all material and relevant facts. Hearsay evidence may for good cause shown be received at the discretion of the Hearing Examiner and accorded such weight as the circumstances warrant.

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(b) The proceedings shall be open only to duly authorized representatives of the staff of the NRC, the individual, his or her counsel or representative, and such persons as may be officially authorized by the Hearing Examiner. Witnesses shall not testify in the presence of other witnesses except that the Hearing Examiner may, at his or her discretion, allow for expert witnesses to be present during testimony relevant to their own testimony.

(c) Witnesses, including the individual, shall be examined under oath or affirmation by the party who called them and may be cross-examined by the other. The Hearing Examiner shall rule on all evidentiary matters, may further examine any witness, and may call for additional witnesses or the production of documentary or other physical evidence if, in the exercise of his or her discretion, such additional evidence is deemed necessary to the resolution of an issue.

(d) If it appears during the hearing that Restricted Data or national security information may be disclosed, the Hearing Examiner shall assure that disclosure is made only to persons authorized to receive it.

(e) The Hearing Examiner may, at any time during the hearing, permit the Hearing Counsel to amend the notification letter to add or modify allegations to be considered. In the event of such an amendment to the notification letter, the individual shall be given an opportunity to answer the amended allegations. If the changes are of such a substantial nature that the individual cannot answer the amended allegations without additional time, the Hearing Examiner shall grant such additional time as he or she deems necessary.

(f) The Hearing Examiner may receive and consider evidence in the form of depositions or responses to interrogatories upon a showing that the witness is not available for good reason such as death, serious illness or similar cause, or in the form of depositions, interrogatories, affidavits or statements with agreement of the parties. The Hearing Examiner may take official notice at any stage of the proceeding, where appropriate, of any fact not subject to reasonable dispute in that it is either (1) generally known within the United States or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned. A party is entitled upon timely request to an opportunity to be heard as to the propriety of taking such official notice. In the absence of prior notification the request may be made after notice is taken.

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(g) Hearing Counsel shall examine and cross-examine witnesses and otherwise assist the Hearing Examiner in such a manner as to bring out a full and true disclosure of all facts, both favorable and unfavorable, having a bearing on the issues before the Hearing Examiner. In performing these duties, the Hearing Counsel shall avoid the attitude of a prosecutor and shall always bear in mind that the proceeding is an administrative hearing and not a trial.

(h) Hearing Counsel shall not participate in the deliberations of the Hearing Examiner, and shall express no opinion to the Hearing Examiner concerning the merits of the case. Hearing Counsel shall also, during the course of the hearing, advise the individual of his or her rights under these procedures when the individual is not represented by counsel or other representative.

(i) The individual shall be afforded an opportunity to cross-examine persons who have made oral or written statements adverse to the individual relating to a controverted issue except that any such statement may be received and considered by the Hearing Examiner without affording such opportunity in either of the following circumstances:

(1) The head of the department or agency supplying the statement certifies that the person who furnished the information is a confidential informant who has been engaged in obtaining intelligence information for the Government and that disclosure of the informant's identity would substantially harm the national interest or would endanger the well-being of the informant.

(2) The Commission has determined, after considering the information furnished by the investigative agency concerning the reliability of the person who furnished the information and the accuracy of the statement concerned, that the statement appears to be reliable and material, and that failure of the Hearing Examiner to receive and consider such statement would, in view of the fact that access authorization and/or employment clearance is being sought, be substantially harmful to the national security and that the person who furnished the information cannot appear to testify due to death, serious illness, or similar cause.

(j) (1) Whenever the procedure under paragraph (i)(1) of this section is used, the individual shall be given a summary of the information which shall be as comprehensive and detailed as the national security permits. (2) Whenever the procedure under paragraph (i)(2) is used, the individual shall be provided the identity of the person and the information to be considered. (3) In both paragraph (i) (1) and (2) procedures, appropriate consideration shall be accorded to the fact that the individual did not have an opportunity to cross-examine such informant or person.

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(k) Records provided by investigative agencies that were compiled as a regular or routine procedure by the business or agency from which obtained, or other physical evidence other than investigative reports, may be received and considered subject to rebuttal without authenticating witnesses, provided that the investigative agency furnished such information to the NRC pursuant to its responsibilities in connection with assisting the NRC in determining the individual's eligibility for access authorization and/or employment clearance.

(l) Records compiled in the regular course of business, or other physical evidence other than investigative reports, relating to a controverted issue which, because they are classified, may not be inspected by the individual, may be received and considered provided that:

(1) The Commission has made a determination that such records or other physical evidence appears to be material;

(2) The Commission has made a determination that failure to receive and consider such records or other physical evidence would, in view of the fact that access authorization and/or employment clearance is being sought, be substantially harmful to the national security; and

(3) To the extent that national security permits, a summary or description of such records or other physical evidence is made available to the individual. In every such case, information as to the authenticity and accuracy of such physical evidence furnished by the investigative agency shall be considered.

(m) If the Hearing Examiner determines that additional investigation of any material information is required, he or she shall request in writing that the Director, Office of Administration, arrange for the investigation and shall specify those issues upon which more evidence is requested and identify, where possible, any persons or sources that might provide the evidence sought.

(n) A written transcript of the entire proceeding shall be made by a person possessing appropriate NRC access authorization and/or employment clearance and, except for portions containing Restricted Data or national security information, or other lawfully withholdable information, a copy of such transcript shall be furnished the individual without cost.

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§ 10.29 Recommendation of the Hearing Examiner.

(a) The Hearing Examiner's findings and recommendation shall be based upon the entire record consisting of the transcript of the hearing, the documentary and other evidence adduced therein, and the letter of notification and answer. The Hearing Examiner shall also consider the circumstances of the receipt of evidence pursuant to § 10.28, the individual's record of past employment, and the nature and sensitivity of the job the individual is or may be expected to perform.

(b) The Hearing Examiner shall make specific findings on each allegation in the notification letter including the reasons for his or her findings, and shall make a recommendation as to the action which should be taken in the case.

(c) The Hearing Examiner's recommendation shall be predicated upon his or her findings. If, after considering all the factors in light of the criteria in this part, the Hearing Examiner is of the opinion that granting or continuing access authorization and/or employment clearance to the individual will not endanger the common defense and security and will be clearly consistent with the national interest, a favorable recommendation shall be made; otherwise, an adverse recommendation shall be made.

(d) The Hearing Examiner shall submit his or her findings and recommendation in a signed report together with the record of the case to the Director, Office Administration, with the least practical delay.

(e) The Hearing Examiner shall not consider the possible impact of the loss of the individual's services upon the NRC program.

§ 10.30 New evidence.

After the close of the hearing, in the event the individual discovers new evidence not previously available or known to him or her, the individual may petition the Hearing Examiner if the Hearing Examiner's recommendation has not yet been issued, or thereafter, the Director, Office of Administration, to reopen the record to receive that evidence. If the Hearing Examiner or the Director, respectively, deem it material and appropriate, the record may be reopened to accept the evidence either by stipulation, with the agreement of the Hearing Counsel, or in a reconvened hearing.

§ 10.31 Actions on the recommendations.

(a) Upon receipt of the findings and recommendation from the Hearing Examiner, and the record, the Director, Office of Administration, shall forthwith transmit it to the Executive Director for Operations who at his or her discretion may return the record to the Director, Office of Administration, for further proceedings by the Hearing Examiner with respect to specific matters designated by the Executive Director for Operations;

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(b)(1) In the event of a recommendation by the Hearing Examiner that an individual's access authorization and/or employment clearance be denied or revoked, the Executive Director for Operations shall immediately notify the individual in writing of the Hearing Examiner's findings with respect to each allegation contained in the notification letter, and that the individual has a right to request a review of his or her case by NRC Personnel Security Review Examiners and of the right to submit a brief in support of his or her contentions. The request for a review shall be submitted to the Executive Director for Operations within five days after the receipt of the notice. The brief shall be forwarded to the Executive Director for Operations, for transmission to the NRC Personnel Security Review Examiners, not later than 10 days after receipt of such notice.

(2) In the event the individual fails to request a review by NRC Personnel Security Review Examiners of an adverse recommendation within the prescribed time, the Executive Director for Operations may at his or her discretion request a review of the record of the case by NRC Personnel Security Review Examiners. The request shall set forth those matters at issue in the hearing on which the Executive Director for Operations desires a review by the NRC Personnel Security Review Examiners.

(c) Where the Hearing Examiner has made a recommendation favorable to the individual, the Executive Director for Operations may at his or her discretion request a review of the record of the case by NRC Personnel Security Review Examiners. If such a request is made, the Executive Director for Operations shall immediately cause the individual to be notified of that fact and of those matters at issue in the hearing on which the Executive Director for Operations desires a review by the NRC Personnel Security Review Examiners. The Executive Director for Operations shall further inform the individual that within 10 days of receipt of this notice, the individual may submit a brief concerning those matters at issue for the consideration of the NRC Personnel Security Review Examiners. The brief shall be forwarded to the Executive Director for Operations for transmission to the NRC Personnel Security Review Examiners.

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(d) In the event of a request for a review pursuant to paragraphs (b) and (c) of this section, the Hearing Counsel may file a brief within 10 days of being notified by the Executive Director for Operations that a review has been requested. The brief shall be forwarded to the Executive Director for Operations for transmission to the NRC Personnel Security Review Examiners.

(e) The Hearing Counsel may also request a review of the case by NRC Personnel Security Review Examiners. The request for review, which shall set forth those matters at issue in the hearing on which the Hearing Counsel desires a review, shall be submitted to the Executive Director for Operations within five days after receipt of the Hearing Examiner's findings and recommendation. Within 10 days of the request for review, the Hearing Counsel may file a brief which shall be forwarded to the Executive Director for Operations for transmission to the NRC Personnel Security Review Examiners. A copy of the request for review, and a copy of any brief filed, shall be immediately sent to the individual. If the Hearing Counsel's request is for a review of a recommendation favorable to the individual, the individual may, within 10 days of receipt of a copy of the request for review, submit a brief concerning those matters at issue for consideration of the NRC Personnel Security Review Examiners. The brief shall be forwarded to the Executive Director for Operations for transmission to the NRC Personnel Security Review Examiners.

(f) The time limits imposed by this section for requesting reviews and the filing of briefs may be extended by the Executive Director for Operations for good cause shown.

(g) In the event a request is made for a review of the record by NRC Personnel Security Review Examiners, the Executive Director for Operations shall forthwith send the record, with all findings and recommendations and any briefs filed by the individual and the Hearing Counsel, to the NRC Personnel Security Review Examiners. If neither the individual, the Executive Director for Operations, nor the Hearing Counsel requests such a review, the final determination shall be made by the Executive Director for Operations on the basis of the record with all findings and recommendations.

§ 10.32 Recommendation of the NRC Personnel Security Review Examiners.

(a) The Executive Director for Operations shall designate three NRC Personnel Security Review Examiners to conduct a review of the record of the case. To qualify as a Review Examiner, the person designated shall have an NRC "Q" access authorization and may be an employee of the NRC, its contractors, agents, or licensees. However, no employee or consultant of the NRC shall serve as Review Examiner reviewing the case of an employee (including a consultant) or applicant for employment with the NRC; nor shall any employee or consultant of an NRC contractor, agent or licensee serve as Review Examiner reviewing the case of an employee (including a consultant) or an applicant for employment of that contractor, agent, or licensee. No Review Examiner shall be selected who has knowledge of the case or of any information relevant to the disposition of it, or who for any reason would be unable to issue a fair and unbiased recommenation.

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(b) The designated Review Examiners shall individually and independently, without consulting or otherwise communicating with one another, consider the matter under review based upon the record supplemented by any brief submitted by the individual or the Hearing Counsel. Review Examiners may request such additional briefs as any of them deems appropriate, which will be obtained by the Executive Director for Operations and provided to each Review Examiner. When a Review Examiner determines that additional evidence or further proceedings are necessary, the record may be returned to the Executive Director for Operations with a recommendation that the case be remanded to the Director, Office of Administration, for appropriate action, which may include returning the case to the Hearing Examiner and reconvening the hearing to obtain additional testimony.

(c) In conducting the review, Review Examiners shall make individual findings and recommendations as to the eligibility or continued eligibility of an individual for access authorization and/or employment clearance on the record supplemented by additional testimony or briefs as have previously been determined by a Review Examiner(s) as appropriate. When additional testimony is taken by the Hearing Examiner, a written transcript of such testimony shall be made by a person possessing appropriate NRC access authorization and/or employment clearance and, except for portions containing Restricted Data or national security information, or other lawfully withholdable information, a copy of such transcript shall be furnished the individual without cost.

(d) The Review Examiners shall not consider the possible impact of the loss of the individual's services upon the NRC program.

(e) If, after considering all the factors in light of the criteria set forth in this part, a Review Examiner is of the opinion that granting or continuing access authorization and/or employment clearance to the individual will not endanger the common defense and security and will be clearly consistent with the national interest, the Review Examiner shall make a favorable recommendation; otherwise, the Review Examiner shall make an adverse recommendation. Each Review Examiner shall individually prepare a report of his or her findings and recommendations and submit the report in writing to the Executive Director for Operations, who shall furnish a copy to the individual. The findings and recommendations shall be fully supported by stated reasons supporting the findings and recommendations.

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§ 10.33 Action by the Executive Director for Operations.

(a) The Executive Director for Operations, on the basis of the record accompanied by all findings and recommendations, shall make a final determination whether access authorization and/or employment clearance shall be granted, denied, or revoked, except when the provisions of § 10.28 (i), (j), or (l) have been used and the Executive Director for Operation's determination is adverse, the Commission shall make the final agency determination.

(b) In making the determination as to whether access authorization and/or employment clearance shall be granted, denied, or revoked, the Executive Director for Operations or the Commission shall give due recognition to the favorable as well as the unfavorable information concerning the individual and shall take into account the value of the individual's services to the NRC's program and the consequences of denying or revoking access authorization and/or employment clearance.

(c) In the event of an adverse determination, the Executive Director for Operations shall promptly notify the individual through the Director, Office of Administration, of his or her decision that access authorization and/or employment clearance is being denied or revoked and of his or her findings with respect to each allegation contained in the notification letter for transmittal to the individual.

(d) In the event of a favorable determination, the Executive Director for Operations shall promptly notify the individual through the Director, Office of Administration.

§ 10.34 Action by the Commission.

(a) Whenever, under the provisions of § 10.28(i), (j), or (l) an individual has not been afforded an opportunity to confront and cross-examine witnesses who have furnished information adverse to the individual and an adverse recommendation has been made by the Executive Director for Operations, the Commission shall review the record and determine whether access authorization and/or employment clearance shall be granted, denied, or revoked, based upon the record.

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(b) When the Commission determines to deny or revoke access authorization and/or employment clearance, the individual shall promptly be notified through the Director, Office of Administration, of its decision that access authorization and/or employment clearance is being denied or revoked and of its findings and conclusions with respect to each allegation contained in the notification letter for transmittal to the individual.

(c) Nothing contained in these procedures shall be deemed to limit or affect the responsibility and powers of the Commission to deny or revoke access to Restricted Data or national security information if the security of the nation so requires. Such authority may not be delegated and may be exercised when the Commission determines that invocation of the procedures prescribed in this part is inconsistent with the national security. Such determination shall be conclusive.

§ 10.35 Reconsideration of cases.

(a) Where, pursuant to the procedures set forth in §§ 10.20 through 10.34, the Executive Director for Operations or the Commission has made a determination granting access authorization and/or employment clearance to an individual, the individual's eligibility for access authorization and/or employment clearance shall be reconsidered only when subsequent to the time of that determination, new derogatory information has been received or the scope or sensitivity of the Restricted Data or national security information to which the individual has or will have access has significantly increased. All new derogatory information, whether resulting from the NRC's reinvestigation program or other sources, will be evaluated relative to an individual's continued eligibility in accordance with the procedures of this part.

(b) Where, pursuant to these procedures, the Commission or Executive Director for Operations has made a determination denying or revoking access authorization and/or employment clearance to an individual, the individual's eligibility for access authorization and/or employment clearance may be reconsidered when there is a bona fide offer of employment and/or a bona fide need for access to Restricted Data or national security information and either material and relevant new evidence is presented, which the individual and his or her representatives are without fault in failing to present before, or there is convincing evidence of reformation or rehabilitation. Requests for reconsideration shall be submitted in writing to the Executive Director for Operations through the Director, Office of Administration. Such requests shall be accompanied by an affidavit setting forth in detail the information referred to above. The Executive Director for Operations shall cause the individual to be notified as to whether his or her eligibility for access authorization and/or employment clearance will be reconsidered and if so, the method by which such reconsideration will be accomplished.

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(c) Where access authorization and/or employment clearance has been granted to an individual by the Director, Division of Security, without recourse to the procedures set forth in §§ 10.20 through 10.34, the individual's eligibility for access authorization and/or employment clearance shall be reconsidered only in a case where, subsequent to the granting of the access authorization and/or employment clearance, new derogatory information has been received or the scope or sensitivity of the Restricted Data or national security information, to which the individual has or will have access, has significantly increased. All new derogatory information, whether resulting from the NRC's reinvestigation program or other sources, will be evaluated relative to an individual's continued eligibility in accordance with the procedures of this part.

Subpart D—Miscellaneous

§ 10.36 Terminations.

In the event the individual is no longer an applicant for access authorization and/or employment clearance or no longer requires such, the procedures of this part shall be terminated without a final determination as to the individual's eligibility for access authorization and/. or employment clearance.

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§ 10.37 Attorney representation.

In the event the individual is represented by an attorney or other representative, the individual shall file with the Director, Office of Administration, a document designating such attorney or representative and authorizing such attorney or representative to receive all correspondence, transcripts, and other documents pertaining to the proceeding under this part.

§ 10.38 Certifications.

Whenever information is made a part of the record under the exceptions authorized by § 10.28 (i), (j), or (l), the record shall contain certificates evidencing that the required determinations have been made.

UNITED STATES NUCLEAR REGULATORY COMMISSION
RULES and REGULATIONS
TITLE 10, CHAPTER 1, CODE OF FEDERAL REGULATIONS—ENERGY

PART 10

CRITERIA AND PROCEDURES FOR DETERMINING ELIGIBILITY FOR ACCESS TO RESTRICTED DATA OR NATIONAL SECURITY INFORMATION

STATEMENTS OF CONSIDERATION

25 FR 6510
Published 7/12/60
Effective 7/12/60

The following regulations of the Commission establishing the criteria and procedures for resolving questions concerning the eligibility of an individual who is not an AEC employee or applicant for AEC employment for access to Restricted Data pursuant to the Atomic Energy Act of 1954, as amended, or for access to defense information, are published to implement Executive Order 10865, 25 F.R. 1583 (February 24, 1960). It should be noted that these rules relate to personnel employed by or applicants for employment with AEC contractors, agents, access permittees, and licensees of the AEC, while the rules contained in Part 4 of the Atomic Energy Commission's rules and regulations relate to criteria and procedures for resolving questions concerning the eligibility of an individual for security clearance for AEC employment under the Atomic Energy Act of 1954, as amended.

Because these regulations relate to the performance of AEC functions as described in section 4(2) of the Administrative Procedure Act of 1946, 5 U.S.C. section 1003(2), the Commission has found that general notice of proposed rulemaking and public procedure thereon are not required and that good cause exists why these rules should be made effective immediately without the customary period of prior notice.

Because of the important nature of the regulations contained herein, the Commission invites written comments from interested members of the public. These comments should be mailed to the General Counsel, U.S. Atomic Energy Commission, Washington 25, D.C.

Pursuant to the Administrative Procedure Act, the following rules are published as a document subject to codification, to be effective immediately upon publication in the FEDERAL REGISTER.

27 FR 4324
Published 5/5/62
Effective 5/5/62

In order to establish uniform procedures for determining the eligibility for access to Restricted Data or defense information under the Government and industrial security programs of the AEC, the Commission is revoking 10 CFR Part 4, "Criteria and Procedures for Determining Eligibility for Security Clearance," and issuing the following amendments to 10 CFR Part 10, "Criteria and Procedures for Determining Access to Restricted Data or Defense Information Within Industry." The amendments to 10 CFR Part 10 establish the criteria and procedures for resolving questions concerning the eligibility of individuals who are employed by or applicants for employment with AEC contractors, agents, access permittees, and licensees of the AEC, individuals who are AEC employees or applicants for AEC employment, and other persons designated by the General Manager of the Atomic Energy Commission, for access to Restricted Data pursuant to the Atomic Energy Act of 1954, as amended, or for access to defense information, and are published to implement Executive Orders 10865, 25 F.R. 1583 (February 24, 1960), and 10450, 18 F.R. 2489 (April 27, 1954).

Because these regulations relate to the performance of AEC functions as described in section 4(2) of the Administrative Procedure Act of 1946, 5 U.S.C. section 1003(2), the Commission has found that general notice of proposed rulemaking and public procedure thereon are not required and that good cause exists why these rules should be made effective immediately without the customary period of prior notice.

Because of the important nature of the regulations contained herein, the Commission invites written comments from interested members of the public. These comments should be mailed to the General Counsel, U.S. Atomic Energy Commission, Washington 25, D.C.

Pursuant to the Administrative Procedure Act, the following rules are published as a document subject to codification, to be effective immediately upon publication in the FEDERAL REGISTER.

32 FR 6836
Published 5/4/67
Effective 5/4/67

On January 10, 1967, the Atomic Energy Commission published in the FEDERAL REGISTER (32 F.R. 234) proposed amendments of its regulation, 10 CFR Part 10, "Criteria and Procedures for Determining Eligibility for Access to Restricted Data or Defense Information", which would clarify, among the security criteria, the one concerning the habitual use of drugs by making it apply explicitly to narcotic and hallucinogenic drugs, and would include as an additional element to be evaluated the single or occasional use of narcotic or hallucinogenic drugs, except as prescribed or administered by a licensed physician.

All interested persons were invited to submit written comments and suggestions for consideration in connection with the proposed amendments within 30 days after publication of the notice of proposed rule making in the FEDERAL REGISTER. Upon consideration of the comments submitted in response to the notice of proposed rule making, none of which opposed the proposed changes, the Commision has adopted the amendments set forth below. These amendments are the same as the proposed amendments published for comment.

Pursuant to the Atomic Energy Act of 1954, as amended, Executive Orders 10450 and 10865, and the Administrative Procedure Act of 1946, as amended, the following amendments of 10 CFR Part 10 are published as a document subject to codification, to be effective upon publication in the FEDERAL REGISTER.

32 FR 13409
Published 9/23/67
Effective 9/23/67

Derogatory Information

Demonstrated financial irresponsibility, and other facts which tend to show that a person is not reliable or trustworthy, or furnish reason to believe that he may be subjected to coercion, influence or pressure which may cause him to act contrary to the best interests of the national security, have long been considered by the Atomic Energy Commission as evidence of conduct which may fall within the criteria of denial of access to classified information set forth in 10 CFR § 10.11. In order to provide more explicit guidance, the Commission has adopted the clarifying amendment set forth below.

Because this amendment relates to the performance of AEC management functions as described in section 4(2) of the Administrative Procedures Act of 1946, as amended, 5 U.S.C., section 553(a)(2), is merely interpretative of existing security criteria, and involves a military, naval, or foreign affairs function of the United States, the Commission has found that general notice of proposed rule making and public procedure thereon are not required and that good cause exists why this amendment should be made effective immediately without the customary period of prior notice.

Because of the importance of the regulations in 10 CFR Part 10, Criteria and Procedures for Determining Eligibility for Access to Restricted Data or Defense Information, and the amendment announced in this notice, the Commission invites written comments from interested members of the public. Comments should be mailed to the Secretary, U.S. Atomic Energy Commission, Washington, D.C. 20545.

Pursuant to the Atomic Energy Act of 1954, as amended, Executive Orders 10450 and 10865, and the Administrative Procedure Act of 1946, as amended, the following amendment of 10 CFR Part 10 is published as a document subject to codification, to be effective upon publication in the FEDERAL REGISTER.

33 FR 9286
Published 6/25/68
Effective 6/25/68

Derogatory Information

An individual's participation in homosexual or other sexually perverted conduct, without adequate evidence of rehabilitation, has long been considered by the Atomic Energy Commission as conduct which may fall within the criteria for denial of access to classified information set forth in 10 CFR § 10.17. In order to provide more explicit guidance to the effect that such conduct, as well as the condition of being a homosexual or other sexual pervert in a technical medical sense, is considered to fall within the criteria, the Commission has adopted the clarifying amendment set forth below. The amendment also explicitly takes into account the materiality of adequate evidence of rehabilitation in evaluating participation in sexually perverted conduct, and declares more explicitly that homosexuality is considered as only one of the types of sexual perversion covered by the criteria.

Because this amendment relates to the performance of agency management functions as described in section 4(2) of the Administrative Procedure Act of 1946, as amended, 5 U.S.C. section 553 (a)(2), is merely interpretative of existing security criteria, and involves a military or foreign affairs function of the United States, the Commission has found that general notice of proposed rule making and public procedure thereon are not required and that good cause exists why this amendment should be made effective immediately without the customary period of prior notice.

Because of the importance of the regulations in 10 CFR Part 10, Criteria and Procedures for Determining Eligibility for Access to Restricted Data or Defense Information, and the amendment which is the subject of this notice, the Commission invites written comments from interested members of the public. These comments should be mailed to the Secretary, U.S. Atomic Energy Commission, Washington, D.C. 20545.

Pursuant to the Atomic Energy Act of 1954, as amended, Executive Orders 10450 and 10865, and the Administrative Procedure Act of 1946, as amended, the following amendment of 10 CFR Part 10 is published as a document subject to codification, to be effective upon publication in the FEDERAL REGISTER.

40 FR 8774
Published 3/3/75
Effective 3/3/75

Energy Reorganization Act: Revision to Chapter 1 to Reflect Organizational and Procedural Changes

See Part 2 Statements of Consideration.

42 FR 54402
Published 10/6/77
Effective 10/6/77

PART 10—CRITERIA AND PROCEDURES FOR DETERMINING ELIGIBILITY FOR ACCESS TO RESTRICTED DATA OR NATIONAL SECURITY INFORMATION

Clarifying and Corrective Amendments

AGENCY: Nuclear Regulatory Commission.

ACTION: Clarifying and corrective amendments.

SUMMARY: The Commission's "Criteria and Procedures for Determining Eligibility for Access to Restricted Data or National Security Information" is hereby amended. The amendments substitute certain office and officer designations so as to reflect the Commission's present staff functions and organization, or to make the designations consistent throughout. The amendments also correct language inaccuracies regarding various statutory provisions of the Atomic Energy Act of 1954, as amended, and delete certain words which are superfluous.

EFFECTIVE DATE: The amendments are effective October 6, 1977.

FOR FURTHER INFORMATION CONTACT:

Royal J. Voegeli, Office of the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone 301-492-7437.

SUPPLEMENTARY INFORMATION: The amendments relate to substituting office and officer designations in 10 CFR Part 10 so as to reflect the present NRC staff functions and organization, or to make the designations consistent throughout Part 10. Thus, the "[AEC] Office of the General Counsel" in § 10.22 will be changed to "Office of the Executive Legal Director", and the definition of "Hearing Counsel" in § 10.5(c) will be changed to mean an NRC attorney assigned "by the Office of the Executive Legal Director." The designation of "Executive Director of Operations" in § 10.22(f) will be changed to "Director, Office of Administration" so that the designation will be consistent with §§ 10.5(b) and 10.26(a). In various other paragraphs the word "Director" has been inserted preceding "Office of Administration", and in others the "Director, Division of Security" has been substituted for "Office of Administration" so that the designations will reflect the actual functioning of the Director of the Division of Security and the delegation of authority currently in effect. Several other changes relate to the routing of documents and staff procedures, and are set forth in the amendments to §§ 10.21, 10.22, 10.22(h), 10.24(a), 10.26(h), 10.27(j) and 10.27(q).

The amendments will also correct language inaccuracies in § 10.3 regarding the statutory provisions of Sections 141, 145(f), 161(a), 161(c) and 161(n) of the Atomic Energy Act of 1954, as amended. The present amendments will also delete certain words which are superfluous, i.e., the word "concerned" in §§ 10.27(j) and 10.30(a), and the words "from whom he received his notification letter" in § 10.29(a).

Because these amendments relate solely to minor matters, it has been found that good cause exists for omitting notice of proposed rule making, and public procedure thereon, as unnecessary, and for making the amendments effective upon publication in the FEDERAL REGISTER.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and section 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 10 are published as a document subject to codification.

➢47 FR 38675
Published 9/2/82
Effective 10/2/82

10 CFR Parts 10, 11, 25, and 95

Revision and Clarification of Criteria and Procedures for Determining Eligibility for Access to Restricted Data or National Security Information or an Employment Clearance and Conforming Amendments

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations to clarify and update the criteria and procedures used for determining the eligibility of an individual for access to Restricted Data or national security information, or an employment clearance. The amendments are in response to an indepth study and analysis to determine and recommend necessary amendments. The amendments will improve the timeliness for reviewing cases by using individual Hearing Examiners and Hearing Review Examiners, clearly distinguishing "access authorization" review procedures in a more logical, clear, and concise manner. This amendment also makes conforming changes to other parts of the Commission's regulations.

EFFECTIVE DATE: October 2, 1982.

FOR FURTHER INFORMATION CONTACT: Mr. Martin J. King, Chief, Personnel Security Branch, Division of Security, U.S. Nuclear Regulatory Commission, Washington, DC 20555, (301) 427-4474.

SUPPLEMENTARY INFORMATION: On May 7, 1982, the Commission published in the **Federal Register** (47 FR 19703) for public comment, proposed amendments to 10 CFR Part 10 of its regulations. Comments were invited, but none were received. No changes have been made to the proposed revisions since publication in the **Federal Register** on May 7, 1982.

As discussed in the statement of considerations that accompanied the proposed rule the Nuclear Regulatory Commission adopted the former Atomic Energy Commission's 10 CFR Part 10 in March 1975. Minor clarifying and corrective amendments were made by the Nuclear Regulatory Commission in 1977.

Staff review subsequently indicated that many of the criteria were outdated and in need of revision. Also, during the rulemaking proceeding on 10 CFR Part 11 some commenters were critical that the rule contained criteria regarding homosexuality and refusal to serve in the armed forces. As a result of these and other comments, a study was undertaken to provide an overall assessment of both the criteria and the procedures for Part 10. Based on the study, the following revision to Part 10 is being proposed.

Access authorization and employment clearance have been defined separately to permit an individual to continue employment even though it may be necessary to suspend the individual's access authorization pending resolution of derogatory information which rasises a question concerning the individual's access eligibility.

The two separate categories of derogatory information criteria, "A" and "B", have been combined in § 10.11 with determination as to eligibility for access authorization and/or employment clearance based upon a comprehensive common-sense judgment, made after consideration of all relevant information, favorable and unfavorable.

The number of criteria listed as examples for consideration in determining eligibility have been reduced from 22 to 13 by combining several of the criteria and eliminating others. Criteria concerning "homosexuality," "refusal to serve in the Armed Forces," and family relatives "residing in a nation whose interest may be inimical to the United States" have been deleted. Also, reference to activities of the spouse have been deleted from the criteria.

Procedures for administrative review hearings have been rewritten and revised. Most significantly, the Personnel Security Board has been replaced by a single Hearing Examiner. Also, the Personnel Security Review Board was eliminated in favor of three Hearing Review Examiners who will individually and independently consider the case under review. Implementation of this system is expected to improve the timeliness in which cases are administratively reviewed under Part 10. As a result of these amendments, conforming amendments to Parts 11, 25, and 95 are also being made.

Regulatory Flexibility Statement

This rule will not have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b). This rule contains modifications to the criteria and procedures for determining the eligibility of individuals for access to Restricted Data, national security information, or an employment clearance. It should not result in any increased costs to licensees.

Paperwork Reduction Act Statement

This final rule contains no new or amended requirements for recordkeeping, reporting, plans or procedures, applications, or any other type of information collection.

List of Subjects in 10 CFR Part 10

Administrative practice and procedure, Classified information, Government employees, Security measures.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and Section 553 of Title 5 of the United States Code, notice is hereby given of the adoption of the following revision to 10 CFR Parts 10, 11, 25, and 95.

The authority citation for Part 10 is presented in the revision of that part. The authority for the amendments to Parts 11, 25, and 95 is Sec. 161, Pub. L. 83-703, 68 Stat. 948 (42 U.S.C. 2201).

PART 11 CRITERIA AND PROCEDURES FOR DETERMINING ELIGIBILITY FOR ACCESS TO OR CONTROL OVER SPECIAL NUCLEAR MATERIAL

General Provisions

Sec.
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Requirements for Special Nuclear Material Access Authorization

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Criteria for Determining Eligibility for Access to, or Control Over, Special Nuclear Material

11.21 Application of the criteria.

Authority: Sec. 7, Pub. L. 93-377, 88 Stat. 475; Sec. 161i, Pub. L. 83-703, 68 Stat. 948 (42 U.S.C. 2201(i)); Sec. 201, as amended, Pub. L. 93-438, 88 Stat. 1242, Pub. L. 94-79, 89 Stat. 413 (42 U.S.C. 5841). Sec. 11.15(e) also issued under the authority of Sec. 501, 65 Stat. 290 (31 U.S.C. 483a).

General Provisions

§ 11.1 Purpose.

This part establishes the requirements for special nuclear material access authorization, and the criteria and procedures for resolving questions concerning the eligibility of individuals to receive special nuclear material access authorization for conduct of certain activities, licensed or otherwise, which involve access to or control over special nuclear material.

§ 11.3 Scope.

(a) The requirements, criteria, and procedures of this part apply to the establishment of and eligibility for special nuclear material access authorization for employees, contractors, consultants of, and applicants for employment with, licensees or contractors of the Nuclear Regulatory Commission where such employment, contract, service, or consultation involves any job falling within the criteria of § 11.11 or § 11.13.

45 FR 76968

(b) The requirements, criteria, and procedures of this part are in addition to and not in lieu of any requirements, criteria, or procedures for access to or control over classified special nuclear material.

§ 11.5 Policy.

It is the policy of the Nuclear Regulatory Commission to carry out its authority to establish and administer, in a manner consistent with traditional American concepts of justice, a personnel security program in the interests of the common defense and security for the purpose of safeguarding special nuclear material and preventing sabotage which would endanger the public by exposure to radiation. To this end, the Commission has established criteria for determining eligibility for special nuclear material access authorization and will afford affected individuals the opportunity for administrative review of questions concerning their eligibility for special nuclear material access authorization.

§ 11.7 Definitions.

As used in this part:

45 FR 76968

(a) Terms defined in Parts 10, 25, 50, 70, 72, 73, and 95 of this chapter have the same meaning when used in this part.

46FR58281

(b) "Special nuclear material access authorization" means an administrative determination that an individual (including a contractor or consultant) who is employed by or is an applicant for employment with an affected Commission contractor, licensee of the Commission, or contractor of a licensee of the Commission may work at a job which affords access to or control over special nuclear material and that permitting the individual to work at that job would not be inimical to the common defense and security.

(c) "NRC-'U' special nuclear material access authorization" means an administrative determination based upon a national agency check and a full-field background investigation conducted by the Office of Personnel Management that an individual in the course of employment is eligible to work at a job falling within the criteria of § 11.11(a)(1) or § 11.13.

(d) "NRC-'R' special nuclear material access authorization" means an administrative determination based upon a national agency check that an individual in the course of employment is eligible to work at a job falling within the criterion of § 11.11(a)(2).

45 FR 76968

11.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). OMB has approved the information collection requirements contained in this part under control number 3150-0062.

(b) The approved information collection requirements contained in this part appear in §§ 11.9, 11.11, 11.13, and 11.15.

49 FR 19623

§ 11.9 Specific exemptions.

The Commission may, upon application of any interested party, grant an exemption from the requirements of this Part. Exemptions will be granted only if they are authorized by law and will not constitute an undue risk to the common defense and security. Documentation related to the request, notification and processing of an exemption shall be maintained for two years beyond the period covered by the exemption.

Requirements for Special Nuclear Material Access Authorization

45 FR 76968

§ 11.11 General requirements.

(a) Each licensee who after February 19, 1981, uses, processes, stores, transports, or delivers to a carrier for transport, formula quantities of special nuclear material (as defined in Part 73 of this chapter) subject to the physical protection requirements of §§ 73.20, 73.25, 73.26, 73.45, and 73.46 of Part 73 of this chapter and each person subject to the general licensing requirements of § 70.20a shall identify at its facility or plant (excluding all non-power reactor facilities and storage of fuel incident thereto and facilities and plants in which the licensee possesses or uses only irradiated special nuclear material subject to the exemption of § 73.6(b) of Part 73 of this chapter), describe, and provide to the Commission, by January 18, 1982, by amendment to its security plan:

46 FR 56598

45 FR 76968

(1) All jobs in which an individual could steal or divert special nuclear material, or commit sabotage which would endanger the public by exposure to radiation, by working alone or in cooperation with an individual who does not possess an NRC-U special nuclear material access authorization, or by directing or coercing any individual to assist in the theft, diversion, or sabotage. Such jobs include but are not limited to:

(i) All positions in the licensee's security force,

(ii) Management positions with the authority to:

(A) Direct the actions of members of the security force or alter security procedures, or

(B) Direct routine movements of special nuclear material, or

(C) Direct the routine status of vital equipment.

(iii) All jobs which require unescorted access within onsite alarm stations.

(iv) All jobs which require unescorted access [2]to special nuclear material or within vital areas.

(2) All jobs which require unescorted access within protected areas and which do not fall within the criterion of paragraph (a)(1) of this section.

(b) After (365 days following Commission approval of the amended security plan submitted in accordance with paragraph (a) of this section) no individual may be permitted to work at any job determined by the Commission to fall within the criterion of paragraph (a)(1) of this section without an NRC-U special nuclear material access authorization, and no individual may be permitted unescorted access to any protected area at any site subject to this part without either an NRC-U or NRC-R special nuclear material access authorization. An exception is provided for any individual employed on the effective date of these amendments, and not yet in receipt of an approved access authorization from the Commission, provided that a complete application was submitted for that employee in accordance with § 11.15 and the application has not been disapproved.

46 FR 56598

§ 11.13 Special requirements for transportation.

(a) All individuals who after 365 days following Commission approval of the amended security plan submitted in accordance with § 11.11(a) transport, arrange for transport, drive motor vehicles in road shipments of special nuclear material, pilot aircraft in air shipments of special nuclear material, act as monitors at transfer points or escort road, rail, sea, or air shipments of special nuclear material subject to the appropriate physical protection requirements of §§ 73.20, 73.25, 73.26, or 73.27 of this chapter shall have NRC-U special nuclear material access authorization. An exception is provided for any individual employed on the effective date of these amendments and not yet in receipt of an approved access authorization from the Commission, provided that a complete application was submitted for that employee in accordance with § 11.15(b) and the application has not been disapproved.

(b) Licensees who after 365 days following Commission approval of the amended security plan submitted in accordance with § 11.11(a) transport or who deliver to a carrier for transport special nuclear material subject to the physical protection requirements of §§ 73.20, 73.25, 73.26, 73.27 of this chapter shall confirm and record prior to shipment the name and special nuclear material access authorization number of all individuals identified in paragraph (a) of this section assigned to the shipment. An exception to the requirement to confirm and record the SSNM access authorization number is provided for any individual employed on the effective date of these amendments and not yet in receipt of an approved access authorization from the Commission, provided that a complete application was submitted for that employee in accordance with § 11.13(a) and the application has not been disapproved.

§ 11.15 Application for special nuclear material access authorization.

(a) Application for special nuclear material access authorization, renewal, or change in level shall be filed by the licensee on behalf of the applicant with the Director, Division of Security, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.[3] Applications for affected individuals employed on the effective date of these amendments shall be submitted within 60 days of notification of Commission approval of the amended security plan.

45 FR 76968

(b) Applications for special nuclear material access authorization shall be made on forms supplied by the Commission including:

(1) A Personnel Security Questionnaire (PSQ) completed by the individual.

(2) Two standard fingerprint cards with the individual's fingerprints (fingerprints may be taken by a local police authority).

(3) Authority to release information.

(4) Security acknowledgment form.

(5) Other related forms where specified in accompanying NRC instructions.

(6) A statement by the employer, prospective employer, or contractor, identifying the job to be assigned to or assumed by the individual and the level of authorization needed, justified by appropriate reference to the licensee's security plan.

(c) Special nuclear material access authorization shall expire 5 years following the date of issue. If continued special nuclear material access authorization is required, an application for renewal shall be submitted at least 120 days prior to expiration date. Failure to make a timely application will result in expiration of special nuclear material access authorization. Special nuclear material access authorization for which a timely application for renewal has been made may be continued beyond the expiration date pending final action on the application. An application for renewal will consist of the following:

(1) A Personnel Security Questionnaire, completed by the applicant.

(2) Two standard fingerprint cards with the individual's fingerprints.

(3) Authority to release information.

(4) Other related forms where specified in accompanying NRC instructions.

(5) A statement by the employer or contractor that at the time of application for renewal the individual's assigned or assumed job requires the level of special nuclear material access authorization which he or she holds, justified by appropriate reference to the licensee's security plan.

(d) If at any time, due to new assignment or assumption of duties, a change in special nuclear material access authorization level from NRC "R" to "U" is required, the individual shall apply for a change of level of special nuclear material access authorization. Such an application shall include a description of the new duties to be assigned or assumed, justified by appropriate reference to the licensee's security plan.

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[2] This does not alter the requirement for methods to observe individuals within material access areas as stated in § 73.46(e)(9) of this chapter.

[3] Process times for special nuclear material access authorizations can be expected to be about 190 days for NRC-U and 130 days for NRC-R.

47 FR 5197 (e) Each application for special nuclear material access authorization, renewal, or change in level shall be accompanied by the licensee's remittance payable to the U.S. Nuclear Regulatory Commission according to the following schedule:

(1) New application, "U"	$1,550
(2) New application, "R"	75
(3) Renewal "U" or "R"	15
(4) Change of level "R" to "U" (full fee charged only if an investigation is required)	[1] 1,550
(5) Convert existing NRC or DOE "Q" or "Q(X)" to U	[1] 1,550
(6) Convert existing NRC or DOE "L" or "L(X)" to U	[1] 1,550
(7) Convert existing NRC or DOE "Q", "Q(X)", "L", or "L(X)" to R	[1] 15

[1] Full fee charged only if an investigation is required, i.e., last investigation is more than five years old or does not meet necessary investigative scope

Material access authorization fees will be published in December of each year and will be applicable to each access authorization request received during the following calendar year. Applications from individuals having current Federal access authorizations may be processed expeditiously at less cost, since the Commission may accept the certification of access authorizations and investigative data (which is less than five years old) from other Federal Government agencies which grant personnel access authorization.

46 FR 56598 (f) Nuclear Regulatory Commission (NRC) or Department of Energy (DOE) "Q" or "L" access authorization granted to an NRC or DOE employee or a Department of Defense (DOD) "Top Secret" (based on a full field investigation) or "Secret" clearance granted to a DOD employee, will permit this employee, on official business, the same level of unescorted access to special nuclear material within material access areas, or within vital areas, or protected areas that an NRC "U" or "R" access authorization, respectively, would afford in accordance with § 11.11.

Criteria for Determining Eligibility for Access to or Control Over, Special Nuclear Material

§ 11.21 Application of the criteria.

45 FR 76968 (a) The decision to grant or deny special nuclear material access authorization is a comprehensive, common-sense judgment, made after consideration of all the relevant information, favorable or unfavorable, that to grant or deny special nuclear material access authorization is or is not inimical to the common defense and security and is or is not clearly consistent with the national interest.

(b) To assist in making these determinations, on the basis of all the information in a particular case, there are set forth in § 10.11 of this chapter a number of specific types of derogatory information. These criteria are not exhaustive but contain the principal types of derogatory information which in the opinion of the Commission create a question as to the individual's eligibility for special nuclear material access authorization. These criteria are subject to continuing review and may be revised from time to time as experience and circumstances may make desirable.

47 FR 38675 (c) When the reports of investigation of an individual contain information reasonably falling within one or more of the classes of derogatory information listed in § 10.11, it shall create a question as to the individual's eligibility for special nuclear material access authorization. In such cases, the application of the criteria shall be made in light of and with specific regard to whether the existence of such information supports a reasonable belief that the granting of a special nuclear material access authorization would be inimical to the common defense and security. The Director, Division of Security, may authorize the granting of special nuclear material access authorization on the basis of the information in the case or may authorize the conduct of an interview with the individual and, on the basis of such interview and such other investigation as the Director deems appropriate, may authorize the granting of special nuclear material access authorization. Otherwise, a question concerning the eligibility of an individual for special nuclear material access authorization shall be resolved in accordance with the procedures set forth in §§ 10.20–10.38 of this chapter.

(d) In resolving a question concerning the eligibility or continued eligibility of an individual for special nuclear material access authorization by action of the Hearing Examiner,[4] the following principle shall be applied by the Examiner: Where there are grounds sufficient to establish a reasonable belief as to the truth of the information regarded as substantially derogatory and when the existence of such information supports a reasonable belief that granting access would be inimical to the common defense and security, this shall be the basis for a recommendation for denying or revoking special nuclear material access authorization if not satisfactorily rebutted by the individual or shown to be mitigated by circumstance.

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[4] The function of the Hearing Examiner is described in Part 10 of this chapter.

PART 11

CRITERIA AND PROCEDURES FOR DETERMINING ELIGIBILITY FOR ACCESS TO OR CONTROL OVER SPECIAL NUCLEAR MATERIAL

STATEMENTS OF CONSIDERATION

45 FR 76968
Published 11/21/80
Effective 2/4/81
Effective date extended*

10 CFR Parts 11, 50, 70

Criteria and Procedures for Determining Eligibility for Access to or Control Over Special Nuclear Material

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: In March 1977, the Commission published for public comment proposed amendments to establish criteria and procedures for determining eligibility for access to or control over special nuclear material. As a result of public and staff comments, the record of an informal Hearing, and the recommendations of the Hearing Board, the scope of the proposed amendments has been narrowed to include only those fuel cycle facilities and transportation activities that use, process, or store formula quantities of special nuclear material. Light water reactors, non-power reactors, and facilities possessing only irradiated special nuclear material subject to the exemption of § 73.6(b) are not covered by these revised amendments. The Nuclear Regulatory commission is now publishing these revised amendments in final form.

EFFECTIVE DATE: February 4, 1981.

FOR FURTHER INFORMATION CONTACT: Frank Gillespie or Jim Prell, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Phone: 301–443–5907.

SUPPLEMENTARY INFORMATION: Section 161i of the Atomic Energy Act of 1954, as amended, permits the Nuclear Regulatory Commission to prescribe regulations instituting a clearance program for those individuals who have access to or control over special nuclear material. Specifically, the section provides that the Commission may issue regulations "* * * designating activities involving quantities of special nuclear material which in the opinion of the Commission are important to the common defense and security, that may be conducted only by persons whose character, associations and loyalty shall have been investigated under standards and specifications established by the commission and as to whom the commission shall have determined that permitting each such person to conduct the activity will not be inimical to the common defense and security * * *."

Pursuant to this statutory authority and after consideration of the results of public comments, the record developed in an informal hearing, and the recommendations of the hearing board, the Commission is issuing regulations which would require certain individuals involved in the operation of licensed fuel reprocessing plants, in the licensed use, processing, or storage of certain quantities of special nuclear materials, and in the transportation by the private sector of certain quantities of special nuclear material, to receive authorization from the Commission for access to or control over special nuclear material. Nuclear power reactors licensed pursuant to 10 CFR Part 50[1] are not covered by these amendments. They will be the subject of a separate rulemaking to include a notice and comment period. Additionally, non-power reactors and storage of fuel incident thereto, have been excluded from the requirements of these amendments pending completion of a separate ongoing review of total safeguards requirements adequacy at such facilities. When that assessment is complete, considerations of access authorization requirements will be included in the evaluation of overall safeguards upgrading which may be considered necessary for these facilities.

Finally, facilities possessing formula quantities of special nuclear material only in the form of irradiated special nuclear material subject to the exemption of § 73.6(b) are also excluded from these requirments as the Commission concludes that the risk of theft or diversion of such material is minimal. This is consistent with other safeguards requirements for irradiated special nuclear material.

These regulations utilize a personnel security program as a measure to protect against those employed in the affected nuclear acitivities who might conspire to steal or divert special nuclear material or conduct sabotage which would endanger the public by exposure to radiation. Of course, a clearance program itself does not entirely solve the problem of the "insider," but, in the opinion of the commission, experience has shown that such programs do substantially reduce the risk. Moreover, the proposed program is one of several elements in the commission's overall safeguards program which together protect against threats, both internal and external.

Two levels of special nuclear material access authorization are established. The higher level, NRC–U, is based upon a full-field background investigation and will apply to (i) all individuals who require unescorted access to special nuclear material or within vital areas, (ii) those jobs in which an individual alone or in conspiracy with another individual who does not possess an NRC–U special nuclear material access authorization could act to steal or divert special nuclear material or to commit sabotage, and (iii) drivers of motor vehicles and pilots of aircraft transporting certain quantities of special nuclear material and those who escort road, rail, air or sea shipments of special nuclear material. The lower level, NRC–R, is based upon a National Agency Check and will apply to all individuals who require unescorted access to protected areas and who are not required to possess an NRC–U special nuclear material access authorization. An implementation schedule has been established to account for changed estimates of the time required to process access authorization applications (190 days for an NRC "U" and 130 days for an NRC "R") and for the initial flow of applications. Jobs at fixed sites requiring access authorization will be identified by licensee submittal of an amendment to the security plan. For jobs not requiring an amended security plan, affected individuals must have the required access authorization within 365 days of the effective date of the amendments. All others must have authorization 365 days after having the amended security plan approved designating those jobs which require access authorization. Excepted from the 365-day implementation in all cases are those who initially apply but have not received notification due to Commission processing time.

Both the National Agency Check and the full-field background investigation are conducted by the Office of Personnel Management. The National Agency check consists of a check of files of the FBI (fingerprint and central files), Office of Personnel Management (Security-Investigative index), and a check of military records and records of other government agencies, as appropriate. The full-field background investigation consists of interviews of references, conducted by investigative agents of the Office of Personnel Management, in addition to the records check. Sources of information developed in the course of the investigation are also interviewed. The full-field background investigation conducted by the Office of Personnel Management generally covers the 5-year period of the individual's adult life prior to the investigation.

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[1] Except for the Fort St. Vrain facility.

*Amended 46 FR 13681

Licensees and license applicants will be required to amend their security plans by identifying and describing jobs at their facilities which require authorization. Affected individuals will be required to obtain authorization according to the schedules set forth in the proposed rule. Individuals who are newly hired or who change jobs where the new job will require a material access authorization must obtain an authorization before beginning the job. Authorization will be renewed every 5 years.

The establishment of a material access authorization program in the licensed nuclear industry will affect individuals who are not employed by any licensee or contractor of the Commission as well as licensee employees. It is the Commission's intent to minimize both the impact on the rights of privacy and association of individuals affected, and the number of individuals affected, while providing an effective measure of protection against those who would seek employment with, or use their position in, the nuclear industry for purposes of theft or sabotage. In preparing these regulations, among the matters considered were the scope of investigations (e.g., whether a full-field background investigation should be required for all individuals), which job functions should require material access authorization (e.g., require authorization only for "key" positions or adopt a graded system with level of clearance determined by job), whether psychological assessment should be required, and the relation of the proposed program to current NRC and DOE personnel security programs.

The Commission also considered the question of whether new criteria should be developed against which a decision for authorization would be made. The present NRC security clearance criteria (10 CFR Part 10) were developed for access to classified information and, as such, not all criteria may be equally significant for questions of access to special nuclear material, and some may not be perceived as relevant in specific cases. Also, there may be cases in which additional criteria, not now included in 10 CFR Part 10, would be more to the point. However, these criteria do correspond to the Federal Government's general approach to personnel security, and specifically, they are presently used for DOE access authorization programs. Furthermore, the criteria are in the nature of guidelines to be used in a decision process characterized by common sense judgments, rather than quantitative criteria. Moreover, the Commission is reluctant to devise a new set of criteria without evidence that such new criteria would significantly improve upon those which presently exist. The Commission notes, however, that the Department of Energy is currently reviewing the criteria applicable to access to Restricted Data and Material and the Commission will review its own criteria in 10 CFR Part 10 in light of any revision made by the Department of Energy in 10 CFR Part 710. Hence, in light of the above, the Commission is relying on the considerable expertise residing in the broad experience of the Federal Government in the area of personnel security programs by proposing the use of the criteria contained in 10 CFR Part 10 as guidelines in deciding questions of access to or control over special nuclear material.

Pursuant to the Atomic Energy Act of 1954, as amended, by the Energy Reorganization Act of 1974, and section 553 of title 5 of the United States Code, notice is hereby given that a new 10 CFR Chapter I, Part 11, and the following conforming amendments to 10 CFR Chapter I, Parts 50 and 70 are published as a document subject to codification.

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46 FR 56598
Published 11/18/81
Effective 12/18/81

10 CFR Part 11

Criteria and Procedures for Determining Eligibility for Access to or Control Over Special Nuclear Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission is amending its regulations to make needed minor revisions and clarifications in previously published requirements for "Criteria and Procedures for Determining Eligibility for Access to or Control Over Special Nuclear Material." The amendments specify a date for submission of security plans to the NRC, specifically identify individuals who are required to submit amended security plans for Commission approval, explicitly allow for the equivalency and acceptability of Department of Energy (DOE), Nuclear Regulatory Commission (NRC), and Department of Defense (DOD) clearances granted to their employees, adjust the fee schedule for obtaining clearances, specify dates for individual applications for clearances, and revise the wording in § 11.15(e) to be consistent with that of § 25.17(e), which references the expeditious processing of applications from individuals having current Federal access authorizations.

EFFECTIVE DATE: December 18, 1981.

FOR FURTHER INFORMATION CONTACT: Kristina Z. Markulis, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, (telephone) 301-443-5976.

SUPPLEMENTARY INFORMATION: On November 21, 1980, the Commission published 10 CFR Part 11 as a final rule (45 FR 76968), to be effective February 4, 1981. Subsequently, the effective date for the application, recordkeeping, and reporting requirements in the rule was extended to March 21, 1981 (46 FR 13681, February 24, 1981). Part 11, "Criteria and Procedures for Determining Eligibility for Access to or Control Over Special Nuclear Material" institutes a clearance program for those individuals who have access to or control over formula quantities of special nuclear material. The Commission now recognizes that the following minor revisions and clarifying amendments are needed:

1. A specific date is needed for each licensee and license applicant to submit to the Commission its amended security plan which incorporates the criteria set forth in the final rule published in the **Federal Register** (45 FR 76968) on November 21, 1980.

2. Clarification is needed in adequately identifying which individuals are required to submit amended security plans for Commission approval. The final rule, 10 CFR Part 11, was not changed to take into account the change to 10 CFR 70.20a relative to carriers which occurred after Part 11 had been published in proposed form. Althought the carriers were not specifically referenced in Part 11 as being required to submit amended security plans, the original requirements published and subject to public comment in Part 11, included the need for amended security plans to be submitted by the shipper for NRC approval as they relate to transportation activities. An amendment is now being

made to clarify and adjust the relationships of licensees to the NRC under Part 11 consistent with their relationship under Part 70. Thus, persons with licenses for activities at fixed sites will only have to submit amended security plans for material access authorizations for personnel working at the site. Persons licensed to transport special nuclear material under the general license in 10 CFR 70.20a will have to submit a revision to the required plan to identify persons in the transportation request who will need to be granted material access authorization under Part 11.

3. A revised fee schedule is needed to reflect the increase in the charge for a full field background investigation. While the final rule establishing Part 11 was before the Commission for final publication approval, the Office of Personnel Mangement (OPM) notified NRC of an increase in the charge. This increase, plus a part of NRC's overhead associated with the processing of these access authorizations, is reflected in the amended section.

4. A minor change is also needed to reflect the acceptance of "Q" and "L" security clearances granted to NRC and DOE employees and the acceptance of "Top Secret" and "Secret" security clearances granted to DOD employees as being equivalent to the respective NRC "U" and "R" access authorization levels required by this Part.

5. The wording in § 11.15(e) needs to be revised to read the same as in § 25.17(e), which became effective October 1, 1980. The paragraph references expeditious processing of applications from individuals having current Federal access authorizations.

6. A specific date for obtaining individual clearances is needed in § 11.13(a).

Since these amendments relate solely to minor technical matters as to interchangeability of clearances, fees, and dates, are clarifying in nature, and since there are only 3 (three) affected persons operating under the general license issued by § 70.20a subject to the referenced requirements of Part 73 (who are already aware of the need to submit a listing of individuals needing access authorization to the Commission) for whom the impact of incorporating the listing by amendment to their security plan is minimal, the Commission has found that good cause exists for omitting notice of proposed rulemaking and public procedure thereon as unnecessary.

For the reasons set out in the preamble and pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendments to Part 11 of Title 10, Chapter 1, Code of Federal Regulations are published as a document subject to codification.

46 FR 58281
Published 12/1/81
Effective 12/1/81

Licensing Requirements for the Storage of Spent Fuel in an Independent Spent Fuel Storage Installation; Minor Clarifying and Conforming Amendments

See Part 72 Statements of Consideration

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47 FR 5197
Published 2/4/82
Effective 2/4/82

10 CFR Part 11

Revision of Access Authorization Fees for Nuclear Industry

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The NRC is amending its regulations establishing the scheduling of fees charged NRC licensees for the performance of full field security background investigations. This amendment makes a minor correction in the schedule and increases the fee to cover the increased fee charged the NRC by the Office of Personnel Management which performs these investigations and to cover increasing costs NRC incurs in processing the access authorization that require the investigations.

EFFECTIVE DATE: February 4, 1982.

FOR FURTHER INFORMATION CONTACT: Duane G. Kidd, Chief, Security Policy Branch, Division of Security, Office of Administration, United States Nuclear Regulatory Commission, Washington, D.C. 20555, (301) 427-4415.

SUPPLEMENTARY INFORMATION: 10 CFR Part 11, "Criteria and Procedures for Determining Eligibility for Access to or Control Over Special Nuclear Material," was first issued on November 21, 1980 (45 FR 76968). Section 11.15 indicates that access authorization fees for the succeeding year will be published each December and will be applicable to each access authorization request received during the following calendar year. The initial fee schedule for this part was published in the Federal Register on November 21, 1980 (45 FR 76968) and first updated along with other minor amendments on November 18, 1981 (46 FR 56598).

These fees are charged for access authorizations processed and services rendered by the Nuclear Regulatory Commission (NRC), at the request of an identifiable recipient of the services, and are authorized under Title V of the Independent Offices Appropriation Act of 1952 (65 Stat. 290; 31 U.S.C. 483a).

The only revisions to the fee schedule in this amendment are a deletion of an improper reference to "R" conversions in item (5) and the increased cost for the processing of an NRC "U" access authorization involving a full field background investigation conducted by the Office of Personnel Management (OPM). The charge to NRC by OPM of this investigation has been raised from $1,200.00 to $1,350.00. The new fee recovers this cost plus a part of NRC's overheard associated with the processing of these access authorizations. The fees for an NRC "R" access authorization have not been changed.

When the original Part 11 fee schedule was developed, and again when recently revised, it was recognized that the actual amount charged to NRC by OPM for conducting investigations would be the decisive factor governing future fees charged by NRC. This relationship between the amounts charged by OPM and the resulting fees charged by NRC still exists and was affected by the recent increase announced by OPM. Since the public had the opportunity to comment on this aspect of Part 11 as a proposed rule, it is not felt that any further benefits would be accrued by additional public comment at this time. Under these circumstances, NRC, for good cause, finds that notice of proposed rulemaking and public procedure thereon are unnecessary. The amendments will become effective February 4, 1982.

Pursuant to the Independent Offices Appropriation Act of 1952 (65 Stat. 290; 31 U.S.C. 483a) and 5 U.S.C. 553, § 11.15 of Part 11 of Title 10, Chapter 1, Code of Federal Regulations, is published as a document subject to codification.

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47 FR 38675
Published 9/2/82
Effective 10/2/82

Revision and Clarification of Criteria and Procedures for Determining Eligibility for Access to Restricted Data or National Security Information or an Employment Clearance and Conforming Amendments

See Part 10 Statements of Consideration

➢ **49 FR 19623**
Published 5/9/84
Effective 5/9/84

Information Collection Requirements;
Display of OMB Control Numbers

See Part 0 Statements of Consideration

PART 14 ADMINISTRATIVE CLAIMS UNDER FEDERAL TORT CLAIMS ACT

PART 14—ADMINISTRATIVE CLAIMS UNDER FEDERAL TORT CLAIMS ACT

Subpart A—General

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Subpart D—Employee Drivers

14.51 Procedures when employee drivers are sued.
14.53 Scope of employment report.
14.55 Removal of state court proceedings.
14.57 Suit against the United States exclusive remedy.

Authority: Sec. 1, 80 Stat. 306 (28 U.S.C. 2672); sec. 2679, 62 Stat. 984 as amended (28 U.S.C. 2679); sec. 161, 68 Stat. 948 as amended (42 U.S.C. 2201); 28 CFR 14.11.

Subpart A—General

§ 14.1 Scope of regulations.

(a) The terms "Nuclear Regulatory Commission" and "NRC" as used in this part mean the agency established by section 201(a) of the Energy Reorganization Act of 1974, but do not include any contractor with the Nuclear Regulatory Commission.

(b) The regulations in this part supplement the Department of Justice's regulations in 28 CFR Parts 14 and 15.

(c) These regulations apply to administrative claims under the Federal Tort Claims Act, as amended, asserted on or after the effective date of this rule, for money damages against the United States for damage to or loss of property or personal injury or death caused by the negligent or wrongful act or omission of any employee of the NRC while acting within the scope of his or her office or employment, under circumstances where the United States, if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission occurred.

(d) These regulations also set forth the procedures when lawsuits are commenced against an employee of the NRC resulting from the operation of a motor vehicle while acting within the scope of his or her employment.

§ 14.3 Limit on attorney fees; penalty.

(a) An attorney may not charge or receive fees in excess of—

(1) 25 percent of any judgment rendered under 28 U.S.C. 1346(b);

(2) 25 percent of any settlement made under 28 U.S.C. 2677; or

(3) 20 percent of any award, compromise, or settlement made under 28 U.S.C. 2672.

(b) Any attorney who charges or receives any amount in excess of that allowed under this section is subject to a fine of not more than $2,000 or imprisonment for not more than one year, or both. (28 U.S.C. 2678)

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Subpart B—Filing Procedures and Requirements

§ 14.11 Who may file a claim.

(a) A claim for damage to or loss of property may be presented by the owner of the property interest which is the subject of the claim, his or her duly authorized agent, or his or her legal representative.

(b) A claim for personal injury may be presented by the injured person, his or her duly authorized agent, or his or her legal representative.

(c) A claim based on death may be presented by the executor or administrator of the decedent's estate, or by any other person legally entitled to assert the claim under applicable State law.

(d) A claim for loss wholly compensated by an insurer with the rights of a subrogee may be presented by the insurer. A claim for loss partially compensated by an insurer with the rights of a subrogee may be presented by the insurer or the insured individually, to the extent of their respective interests, or jointly. Whenever an insurer presents a claim asserting the rights of a subrogee, the insurer shall present with the claim appropriate evidence that the insurer has the rights of a subrogee.

(e) If a claim is presented by an agent or legal representative that person shall—

(1) Present the claim in the name of the claimant;

(2) Sign the claim;

(3) Show the title or legal capacity of the person signing the claim; and

(4) Include with the claim evidence of his or her authority to present a claim on behalf of the claimant as agent, executor, administrator, parent, guardian, or other representative.

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§ 14.13 When is a claim presented to NRC.

For purposes of the provisions of 28 U.S.C. 2672, a claim is presented when NRC receives from a claimant, or the claimant's duly authorized agent or legal representative, an executed Standard Form 95 or other written notification of an incident. An executed Standard Form 95 or written notification must be accompanied by a claim for money damages in a sum certain for damage to or loss of property, personal injury, or death alleged to have occurred by reason of the incident.

§ 14.15 Where to present a claim to NRC.

A claimant shall mail or deliver the claim to the office of employment of the NRC employee whose negligent or wrongful act or omission is alleged to have caused the loss or injury. If the office of employment is not known, the claimant shall file the claim with the Office of the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

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§ 14.17 A claim must be presented to the appropriate agency.

A claimant shall present the claim to the Federal agency whose activities gave rise to the claim. If a claim is erroneously presented to the NRC, the NRC shall transfer it to the appropriate agency, if the proper agency can be identified from the claim, and shall advise the claimant of the transfer. If transfer is not feasible, the NRC shall return the claim to the claimant. The fact of transfer does not, in itself, preclude further transfer, return of the claim to the claimant, or other appropriate disposition of the claim. A claim shall be presented, as required by 28 U.S.C. 2401(b), as of the date it is received by the appropriate agency.

§ 14.19 When a claim is filed with more than one agency.

(a) If the NRC and one or more other Federal agencies is or may be involved in the events giving rise to the claim, and if the claim is filed with the NRC, the NRC shall contact all other affected agencies in order to designate the single agency which will investigate and decide the merits of the claim.

(1) In the event that an agreed upon designation cannot be made by the affected agencies, the Department of Justice will be consulted and will designate a primary agency to investigate and decide the merits of the claim. If the NRC is designated as the primary agency, it shall notify the claimant that all future correspondence concerning the claim shall be directed to the NRC.

(2) All involved Federal agencies can agree either to conduct their own administrative reviews and to coordinate the results or to have the investigations conducted by the primary agency. In either event, the primary agency is responsible for the final determination of the claim.

(b) A claimant presenting a claim arising from an incident to more than one agency should identify each agency to which the claim is submitted at the time each claim is presented. If a claim arising from an incident is presented to more than one Federal agency without any indication that more than one agency is involved, and any one of the concerned Federal agencies takes final action on that claim, the final action is conclusive on the claims presented to the other agencies in regard to the time required for filing suit set forth in 28 U.S.C. 2401(b). However, if NRC, as a subsequently involved Federal agency, desires to take further action with a view towards settling the claim, the NRC may treat the matter as a request for reconsideration of the final denial under 10 CFR 14.39, unless suit has been filed in the interim, and advise the claimant of the action.

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§ 14.21 Filing a claim after an agency final denial.

If, after a final denial by another agency, the claimant files with the NRC a claim arising out of the same incident on which the claim filed with the other agency was based, the submission of the claim to NRC will not toll the requirement of 28 U.S.C. 2401(b) that suit must be filed within six months of the final denial by the other agency, unless the other agency specifically and explicitly treats the submission to NRC as a request for reconsideration under 10 CFR 14.39 and advises the claimant of the action.

§ 14.23 Evidence and information to be submitted.

(a) *Death.* In support of a claim based on death, the claimant may be required to submit the following evidence or information:

(1) An authenticated death certificate or other competent evidence showing cause of death, date of death, and age of decedent.

(2) Decedent's employment or occupation at time of death, including his or her monthly or yearly salary or earnings (if any), and the duration of his or her last employment or occupation.

(3) Full names, addresses, birth dates, kinship, and marital status of the decedent's survivors, including identification of those survivors who were dependent for support upon the decedent at the time of death.

(4) Degree of support afforded by the decedent to each survivor dependent upon him or her for support at the time of death.

(5) Decedent's general physical and mental condition before death.

(6) Itemized bills for medical and burial expenses incurred by reason of the incident causing death, or itemized receipts of payment for these expenses.

(7) If damages for pain and suffering prior to death are claimed, a physician's detailed statement specifying the injuries suffered, duration of pain and suffering, any drugs administered for pain, and the decedent's physical condition in the interval between injury and death.

(8) Any other evidence or information which may have a bearing on either the responsibility of the United States for the death or the amount of damages claimed.

(b) *Personal injury.* In support of a claim for personal injury, including pain and suffering, the claimant may be required to submit the following evidence or information:

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(1) A written report by the attending physician or dentist setting forth the nature and extent of the injury, nature and extent of treatment, any degree of temporary or permanent disability and prognosis, period of hospitalization, and any diminished earning capacity. In addition, the claimant may be required to submit to a physical or mental examination by a physician employed by the NRC or another Federal agency. The claimant may request in writing a copy of the report of the examining physician if the claimant has—

(i) Furnished the report referred to in paragraph (a)(1) of this section on request; and

(ii) Made or agrees to make available to the NRC all other reports of the claimant's physical or mental condition which have been or are made by any physician.

(2) Itemized bills for medical, dental, and hospital expenses incurred, or itemized receipts of payment for these expenses.

(3) If the prognosis reveals the necessity for future treatment, a statement of expected expenses for the treatment.

(4) If a claim is made for loss of time from employment, a written statement from his or her employer showing actual time lost from employment, whether he or she is a full- or part-time employee, and wages or salary actually lost.

(5) If a claim is made for loss of income and the claimant is self-employed, documentary evidence

showing the amount of earnings actually lost.

(6) Any other evidence or information which may have a bearing on either the responsibility of the United States for the personal injury or the damages claimed.

(c) *Property damage.* In support of a claim for damage to or loss of property, real or personal, the claimant may be required to submit the following evidence or information:

(1) Proof of ownership of the property interest which is the subject of the claim.

(2) A detailed statement of the amount claimed with respect to each item of property.

(3) An itemized receipt of payment for necessary repairs or itemized written estimates of the cost of these repairs.

(4) A statement listing date of purchase, purchase price, and salvage value, where repair is not economical.

(5) Any other evidence or information which may have a bearing on either the responsibility of the United States for the injury to or loss of property or the damages claimed.

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§ 14.25 Amending a claim.

The claimant may amend a claim presented in compliance with 10 CFR 14.13 at any time prior to final agency action or prior to the exercise of the claimant's option under 28 U.S.C. 2675(a). The claimant or his or her duly authorized agent or legal representative shall sign each amendment and submit it in writing. Upon the timely filing of an amendment to a pending claim, the agency shall have six months in which to make a final disposition of the claim as amended and the claimant's option under 28 U.S.C. 2675(a) does not accrue until six months after the filing of an amendment.

§ 14.27 Time limit.

The claimant shall furnish evidence and information of the types described in 10 CFR 14.23, to the extent reasonably practicable, when the claim is initially presented. If the claimant fails to furnish sufficient evidence and information within six months after the claim was initially presented to enable NRC to adjust, determine, compromise and settle the claim, NRC may consider the claim a nullity.

Subpart C—Commission Action and Authority

§ 14.31 Investigation.

The NRC may—

(a) Require the claimant to furnish any evidence or information which is relevant to its consideration of the claim;

(b) Examine the claimant; or

(c) Investigate, or request any other Federal agency to investigate, a claim filed under this part.

§ 14.33 Officials authorized to act.

The Executive Legal Director or the Executive Legal Director's designee shall exercise the authority to adjust, determine, compromise and settle a claim under the provisions of 28 U.S.C. 2672.

§ 14.35 Limitation on NRC's authority.

(a) The NRC shall effect an award, compromise, or settlement of a claim hereunder in excess of $25,000 only with the prior written approval of the Attorney General or his designee. For the purposes of this paragraph, a principal claim and any derivative or subrogated claim are treated as a single claim.

(b) The NRC may adjust, determine, compromise, or settle a claim under this part only after consultation with the Department of Justice if, in the opinion of the Office of the Executive Legal Director—

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(1) A new precedent or a new point of law is involved;

(2) A question of policy is or may be involved;

(3) The United States is or may be entitled to indemnity or contribution from a third party and the NRC is unable to adjust the third party claim; or

(4) The compromise of a particular claim, as a practical matter, will or may control the disposition of a related claim in which the amount to be paid may exceed $25,000.

(c) The NRC may adjust, determine, compromise, or settle a claim under this part only after consultation with the Department of Justice if the NRC is informed or is otherwise aware that the United States, or an employee, agent, or cost-plus contractor of the United States, is involved in litigation based on a claim arising out of the same incident or transaction.

(d) When Department of Justice approval or consultation is required under this section or the advice of the Department of Justice is otherwise requested, the NRC shall direct the referral or request to the Assistant Attorney General, Civil Division, Department of Justice, in writing. The NRC shall ensure that the referral or request contains—

(1) A short and concise statement of the facts and the reasons for the referral or request;

(2) Copies of relevant portions of NRC's claim file; and

(3) A statement of the recommendations or views of the NRC.

A referral or request to the Department of Justice may be made at any time after presentment of a claim to the NRC.

§ 14.37 Final denial of claim.

The NRC shall send notice of a final denial of a claim in writing to the claimant, his or her attorney or legal representative, by certified or registered mail. The notification of final denial may include a statement of the reasons for the denial. The NRC shall include a statement in the notification of final denial that, if the claimant is dissatisfied with NRC's action, he or she may file suit in an appropriate U.S. District Court not later than 6 months after the date of mailing of the notification.

§ 14.39 Reconsideration of a claim.

Prior to the commencement of suit and prior to the expiration of the 6-month period provided in 28 U.S.C. 2401(b), a claimant, or his or her duly authorized agent, or legal representative, may file a written request with the NRC for reconsideration of a final denial of a claim. Upon the timely filing of a request for reconsideration, the NRC shall have 6 months from the date of filing in which to make a final disposition of the claim, and the claimant's option under 28 U.S.C. 2675(a) does not accrue until 6 months after the filing of a request for reconsideration. Final NRC action on a request for reconsideration shall be effected in accordance with the provisions of 10 CFR 14.37.

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§ 14.41 Payment of approved claims.

(a) The NRC shall pay any award, compromise, or settlement in an amount of $2,500 or less made under the provisions of 28 U.S.C. 2672 out of the appropriations available to it. The NRC shall obtain payment of any award, compromise, or settlement in excess of $2,500 from the Department of the Treasury by forwarding Standard Form 1145 to the Payment Branch, Claims Group, General Accounting Office. If an award, compromise, or settlement is in excess of $25,000, Standard Form 1145 must be accompanied by evidence that the award, compromise, or settlement has been approved by the Attorney General or the Attorney General's designee. When the use of Standard Form 1145 is required, it must be executed by the claimant or it must be accompanied by either a claims settlement agreement or a Standard Form 95 executed by the claimant.

(b) If a claimant is represented by an attorney, the voucher for payment must designate both the claimant and his or her attorney as payees, and the check must be delivered to the attorney whose address appears on the voucher.

§ 14.43 Acceptance of payment constitutes release.

Acceptance by the claimant, his agent, or legal representative, of any award, compromise, or settlement made under the provisions of 28 U.S.C. 2672 or 2677, is final and conclusive on the claimant, his or her agent or legal representative and any other person on whose behalf or for whose benefit the claim has been presented. Acceptance constitutes a complete release of any claim against the United States and against any employee of the Government whose act or omission gave rise to the claim.

Subpart D—Employee Drivers

§ 14.51 Procedures when employee drivers are sued.

(a) Any NRC employee against whom a civil action or proceeding is brought for damage to property, or for personal injury or death, on account of the employee's operation of a motor vehicle in the scope of his or her office or employment with the NRC, shall promptly deliver all process and pleadings served upon the employee, or an attested true copy, to the Office of the Executive Legal Director. If the action is brought against an employee's estate, this procedure applies to the employee's personal representative.

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(b) In addition, upon the employee's receipt of any process or pleadings, or any prior information regarding the commencement of a civil action or proceeding, the employee shall immediately advise the Office of the Executive Legal Director by telephone or telegraph.

(c) The Executive Legal Director or designee shall promptly inform the General Counsel of NRC concerning the commencement of the action and furnish to the General Counsel:

(1) Copies of all process and pleadings, and

(2) Copies of all accident, police, and investigation reports and other evidence relating to the action or proceeding.

§ 14.53 Scope of employment report.

Copies of the documents received by the General Counsel from the Executive Legal Director and a report containing all data bearing upon the question whether the employee was acting within the scope of his or her office or employment will be furnished by the General Counsel or designee to the United States Attorney for the district encompassing the place where the civil action or proceeding is brought. A copy of such documents and the report also will be furnished to the Director of the Torts Branch, Civil Division, Department of Justice, at the earliest possible date, or within the time specified by the United States Attorney.

§ 14.55 Removal of state court proceedings.

Upon a certification by the United States Attorney that the defendant employee was acting within the scope of his or her office or employment at the time of the incident out of which the suit arose, any civil action or proceeding commenced in a State court may be removed to the district court of the United States for the district and division encompassing the place where the action or proceeding is pending in accordance with 28 U.S.C. 2679.

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§ 14.57 Suit against United States exclusive remedy.

The remedy against the United States provided by 28 U.S.C. 1346(b) and 2672 for damage to or loss of property or personal injury or death, resulting from the operation by an employee of the Government of any motor vehicle while acting within the scope of his or her office or employment, is exclusive of any other civil action or proceeding by reason of the same subject matter against the employee or his or her estate whose act or omission gave rise to the claim.

PART 14

ADMINISTRATIVE CLAIMS UNDER FEDERAL TORT CLAIMS ACT

STATEMENTS OF CONSIDERATION

47 FR 8983
Published 3/3/82
Effective 3/3/82

10 CFR Part 14

Administrative Claims Under Federal Tort Claims Act

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Federal Tort Claims Act authorizes each Federal agency, in accordance with regulations prescribed by the Attorney General, to administratively settle any claim for damages against the United States caused by the negligent or wrongful act or omission of any employee of the agency while acting within the scope of his or her employment. The Nuclear Regulatory Commission is amending its regulation on administrative claims under the Federal Tort Claims Act to make it current and consistent with regulation of the Attorney General, 28 CFR Part 14, to change the office where claims are filed and the NRC officials who are authorized to act on claims, and to provide procedures when NRC emloyee drivers are sued in State courts.

EFFECTIVE DATE: March 3, 1982.

FOR FURTHER INFORMATION CONTACT: Mr. David J. Clarke, Office of the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (Phone 301-492-7241).

SUPPLEMENTARY INFORMATION: The amended regulation, in addition to the matters stated in the Summary above, primarily—

(1) Requires claimants, to the extent reasonably practicable, to furnish evidence and information of specified types when the claim is initially presented;

(2) Informs claimants that if such evidence and information is not furnished within 6 months, the claim will be considered a nullity;

(3) Adopts 28 CFR 14.10 regarding the funds from which claims are paid;

(4) Provides that when an NRC employee driver was acting within the scope of his or her employment, the remedy against the United States is exclusive; and

(5) Provides limits on attorney fees and provides penalties for exceeding the limits.

Comment Received

Only one comment was received. The commenter observed that since the reorganization of the Civil Division, Department of Justice, the title and organization should be changed from "Chief of Torts Section" to "Director of the Torts Branch." This change was made.

Environmental Impact Statement

This final rule does not significantly affect the environment. An environment impact statement is not required under the National Environmental Policy Act of 1969.

Paperwork Reduction Act

Although the final rule may require the "collection of information" as that term is defined in the Paperwork Reduction Act, the exemption provided by the Act applies to this final rule. The filing of an administrative claim is a statutory prerequisite to the commencement of a civil action against the United States. 28 U.S.C. 2675(a). The furnishing of evidence and information in support of a claim may be required during the conduct of an administrative action involving the NRC against an individual claimant. The collection of such evidence and information is therefore exempt under 44 U.S.C. 3518. The final rule imposes no requirement on persons or entities to maintain specified information, except to the extent necessary to furnish evidence and information in support of a claim.

Regulatory Flexibility Certification Statement

In accordance with sec. 605(b) of the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the undersigned hereby certifies that this rule will not have a significant economic impact on a substantial number of small entities.

During the past 4 years, approximately 48 claims were filed with the NRC under the Federal Tort Claims Act. Of these, 22 were filed by car rental agencies and were allowed in the average amount of $242.00; 18 were filed by individuals and were allowed in the average amount of $1,562.00; 6 were for personal injuries alleged to have resulted from radiation accidents or at testing sites and were transferred to other agencies; and 2 were for losses alleged to have resulted from the shut down of nuclear power plants. One of the 2 was filed by the Commonwealth of Massachusetts which asserted losses of $7,740,000.00. The owners of Three Mile Island filed the other claim and asserted losses of $4,010,000,000.00. Both of those claims were denied. NRC's disposition of claims filed under the Federal Tort Claims Act indicates that these requirements do not have an adverse economic impact on small entities. In addition, the final rule is limited to procedural and conforming amendments that do not have an economic impact on any potential claimant. It appears, therefore, that the final rule will not have a significant economic impact on a substantial number of small entities.

The Final Rule

For the reasons set out in the preamble and pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, section 553 of Title 5, United States Code, the Federal Tort Claims Act, as amended (28 U.S.C. 1346b and 2671–2680) and the regulations of the Department of Justice, as amended (28 CFR Parts 14 and 15), notice is hereby given that the Commission hereby adopts the following amendment to 10 CFR Part 14.

PART 15

DEBT COLLECTION PROCEDURES

PART 15—DEBT COLLECTION PROCEDURES

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Authority: Secs. 161, 186, 68 Stat. 948, 955, as amended (42 U.S.C. 2201, 2236); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); sec. 3, Pub. L. 89–508, 80 Stat. 309 (31 U.S.C. 952); Federal Claims Collection Standards, 4 CFR 101–105.

Subpart A—Application and Coverage

§ 15.1 Application.

(a) These procedures apply to claims for the payment of debts owed to the United States in the form of money or property unless a different procedure is specified in a statute, regulation, or contract. For some debts these procedures apply after special statutory and administrative procedures are exhausted.

(b) The following are examples of kinds of debts to which special statutory and administrative procedures apply:

(1) A claim against an employee for erroneous payment of pay and allowances subject to waiver under 5 U.S.C. 5584 (travel and transportation expenses and allowances and relocation expenses are not subject to waiver under 5 U.S.C. 5584).

(2) A claim involved in a case pending before any Federal Contract Appeals Board or Grant Appeals Board. However, nothing in this part prevents negotiation and settlement of a claim pending before a Board.

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§ 15.3 Communications.

Unless otherwise specified, all communications concerning the regulations in this part should be addressed to the Controller, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Communications may be delivered in person at the Commission's offices at 1717 H Street, NW, Washington, D.C. or at 7920 Norfolk Avenue, Bethesda, Md.

§ 15.5 Claims that are covered.

(a) These procedures generally apply to any claim for payment of a debt which—

(1) Results from activities of the NRC; or

(2) Is referred to the NRC for collection.

(b) These procedures do not apply to—

(1) A claim based on a civil monetary penalty for violation of a licensing requirement. Procedures for this type of claim are provided for in § 2.205 of this chapter;

(2) A claim as to which there is an indication of fraud, the presentation of a false claim, or misrepresentation on the part of the debtor or any other party having an interest in the claim;

(3) A claim based in whole or in part on conduct in violation of the antitrust laws; and

(4) A tax claim, as to which differing exemptions, administrative considerations, enforcement considerations, and statutes apply.

§ 15.7 Monetary limitation on NRC's authority.

The NRC's authority to compromise a claim or to terminate or suspend collection action on a claim covered by these procedures is limited by 31 U.S.C. 952(b) to claims that—

(a) Have not been referred to another Federal Agency, including the GAO, for further collection action; and

(b) Do not exceed $20,000, exclusive of interest (the monetary limitation).

§ 15.9 Omissions not a defense.

(a) The failure of the NRC to include in this part any provision of the Federal Claims Collection Standards does not prevent the NRC from applying the provision.

(b) A debtor may not use the failure of the NRC to comply with any provision of this part or of the Federal Claims Collections Standards as a defense.

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§ 15.11 Conversion claims.

These procedures are directed primarily to the recovery of money on behalf of the Government. The NRC may demand—

(a) The return of specific property; or

(b) Either the return of property or the payment of its value.

§ 15.13 Subdivision of claims.

The NRC shall consider a debtor's liability arising from a particular transaction or contract as a single claim in determining whether the claim is less than the monetary limitation for the purpose of compromising or suspending or terminating collection action. A claim may not be subdivided to avoid the monetary limitation.

Subpart B—Administrative Collection of a Claim

§ 15.21 Written demands for payment.

(a) The NRC shall make appropriate written demands upon the debtor for payment of money or the return of specific property in terms which specify—

(1) The basis of the indebtedness;

(2) The amount claimed;

(3) A description of any property which is to be returned by a date certain;

(4) The date payment is due (The due date is normally 30 days from the date of the initial written demand. The NRC may determine that circumstances warrant an earlier or later due dated);

(5) The rate of interest used to determine the late payment charge if the debt is not paid in full on or before the due date; and

(6) The applicable policy for reporting the delinquent debt to commercial credit bureaus.

(b) Unless a debtor is a current NRC employee, the NRC shall normally send three progressively stronger written demands at approximately 30-day intervals, unless circumstances indicate that alternative remedies better protect the Government's interest, that the debtor has explicitly refused to pay, or that sending additional demands is useless. Depending upon the circumstances of the particular case, the second and third demands may—

(1) Offer or seek to confer with the debtor;

(2) State the amount of the late payment charge that will be added to the debt each 30 days until the debt is paid (the charge for a full 30-day period will also be applicable to periods of less than 30 days); and

(3) State that the authorized collection procedures include any procedure authorized in this part including—

(i) Contacts with the debtor's employer when the debtor is employed by the Federal Government or is a member of the military establishment or the Coast Guard;

(ii) Possible referral of the debt to a private agency for collection;

(iii) The suspension or revocation of a license or other remedy under § 15.29;

(iv) Installment payments possibly requiring security; and

(v) The right to refer the claim to the GAO or the DOJ for litigation.

(c) The NRC shall normally send only one written demand to a debtor who is a current NRC employee. The NRC follows the procedures described in § 15.33 if full payment is not received by the due date specified in the written demand. If the NRC cannot obtain full payment by following the procedures described in § 15.33, the NRC may follow other collection procedures described in this subpart.

(d) The failure to state in a letter of demand a matter described in § 15.21 is not a defense for a debtor and does not prevent the NRC from proceeding with respect to that matter.

§ 15.23 Telephone inquiries and investigations.

(a) If a debtor has not responded to one or more written demands, the NRC shall make reasonable efforts by telephone to determine the debtor's intentions. If the debtor cannot be reached by telephone at the debtor's place of employment, the NRC may telephone the debtor at his or her residence between 7:00 a.m. and 10:00 p.m.

(b) The NRC may undertake an investigation to locate a debtor if the whereabouts of a debtor is a problem, or if a debtor cannot be contacted by telephone.

(c) The NRC, under 15 U.S.C. 1681(f), may obtain consumer credit information from private firms, including the name, address, former addresses, place of employment, and former places of employment of a debtor.

§ 15.25 Personal interviews.

(a) The NRC shall seek an interview with the debtor at the office of the NRC when—

(1) A matter involved in the claim needs clarification;

(2) Information is needed concerning the debtor's circumstances; or

(3) An agreement for payment might be negotiated.

(b) The NRC shall grant an interview with a debtor upon the debtor's request. The NRC will not reimburse a debtor's interview expenses.

§ 15.27 Contact with debtor's employing agency.

If a debtor is employed by the Federal government or is a member of the military establishment or the Coast Guard, and collection by offset cannot be accomplished in accordance with 5 U.S.C. 5514, the NRC shall contact the employing agency to arrange with the debtor for payment of the indebtedness by allotment or otherwise.

§ 15.29 Suspension or revocation of license.

If an applicant or a licensee fails to pay a debt by the due date, the NRC may suspend or revoke the license or approval involved, if any. For any inexcusable, prolonged or repeated failure of a debtor to pay a debt, NRC may suspend or revoke any license or other privilege which NRC has granted to the debtor. Prior to suspending or revoking any license for failure to pay a debt, the NRC will issue to the debtor an order to show cause why the license or approval should not be suspended or revoked.

§ 15.31 Disputed debts.

(a) A debtor who disputes a debt shall explain why the debt is incorrect in fact or in law before the due date specified in the initial demand letter. The debtor may support the explanation by affidavits, cancelled checks, or other relevant evidence.

(b) If the debtor's arguments appear to have merit, the NRC may extend the due date pending a final determination of the existence or amount of the debt.

(c) The NRC may investigate the facts involved in the dispute and, if it considers it necessary, arrange for a conference at which the debtor may present evidence and any arguments in support of the debtor's position.

§ 15.33 Collection by offset.

(a) The NRC may administratively undertake collection by offset on each claim which is liquidated or certain in amount.

(b) The following procedures apply when the NRC seeks to collect a debt by offset against accrued pay, compensation, accrued benefits or the amount of retirement credit due to a present or former Government employee.

(1) The NRC shall effect collection by offset from a person receiving pay or compensation from the Federal Government over a period not greater than the period during which such pay or compensation is to be received. If the debt arises out of an erroneous payment made by NRC to or on behalf of an employee, collection by offset is made in accordance with 5 U.S.C. 5514 and the provisions of paragraph (b) of this section.

(2) If employment is expected to continue during the period of the anticipated collection by offset—

(i) The NRC shall provide the debtor a written demand as provided in § 15.21(a) prior to collecting any indebtedness by offset. The NRC shall also include in the written demand—

(A) Notice of the NRC's intention to collect by offset;

(B) An opportunity to request reconsideration of the debt, or if provided for by statute, waiver of the debt; and

(C) An explanation of the debtor's rights under this subpart.

(ii) The NRC shall accord the debtor an opportunity for a pre-offset oral hearing when—

(A) The debtor requests a waiver of indebtedness and the waiver determination turns on an issue of credibility or veracity; or

(B) The individual requests reconsideration of the debt and the NRC determines that the question of the indebtedness cannot be resolved by review of the documentary evidence.

(iii) If a determination that a debt exists and is certain an amount can be satisfactorily made by review of the documentary evidence and no issues of credibility and veracity exist, then the NRC provides the debtor a written demand as provided in paragraph (b)(2)(i) of this section but does not provide an opportunity for an oral hearing before offsetting the debt.

(3) If the time prior to termination of a debtor's employment does not permit a pre-offset hearing to which the debtor is otherwise entitled under paragraph (b)(2)(ii) of this section, the following provisions apply:

(i) The NRC shall send or provide the debtor a written demand as provided in paragraph (b)(2)(i) of this section.

(ii) The NRC may withhold a sum not greater than the amount of the alleged indebtedness from the amounts accruing to the individual on termination if the NRC determines that—

(A) Amounts accruing to the debtor on termination are available for offset to satisfy the alleged indebtedness; and

(B) The amounts would not be available for offset after termination.

(iii) The NRC shall promptly provide an opportunity for an oral hearing to resolve the issue of indebtedness or waiver after termination of the debtor's employment.

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(iv) The NRC shall promptly refund any amount withheld but later determined not owed the United States.

(4) The form of hearings, when granted, depends on the nature of the transactions giving rise to the debts and the complexity of the issues in dispute. For the vast majority of claims, informal conferences before an official of the NRC is sufficient. Conferences may be conducted by telephone if the debtor elects not to appear in person at the debtor's expense at the place designated for the conference or hearing. The NRC shall maintain at least a summary record of the hearing accorded to the debtor.

(c) If the debtor has obtained a judgment against the United States, any offset against the judgment is accomplished in accordance with the Act of March 3, 1875, 18 Stat. 481, as amended, 31, U.S.C. 227.

(d) The NRC shall make appropriate use of the cooperative efforts of other agencies, including use of the Army Holdup List, in effecting collections by offset. The Army Holdup List is a list of contractors indebted to the United States.

§ 15.35 Payments.

(a) *Payment in full.* The NRC shall collect a claim in full prior to the due date whenever possible. If a debt is paid in one lump sum after the due date, the NRC shall impose a late payment charge. The NRC may waive a late payment charge if it is determined that the amount is negligible in relation to the administrative cost of processing installment payments or that waiver is advisable to induce payment in full.

(b) *Payment in installments.* If a debtor furnishes satisfactory evidence of inability to pay a claim in full prior to the due date, payments in installments may be arranged. Evidence may consist of a financial statement or a signed statement that the debtor's application for a loan to enable the debtor to pay the claim in full was rejected. Except for a debt described at 5 U.S.C. 5514, all installment payment arrangements shall be reduced to writing and require the payment of interest. Installment note forms, including confess judgment notes, may be used. If the debtor's financial statement discloses the ownership of assets which are free and clear of liens or security interests, or assets in which the debtor owns an equity, the debtor may be asked to secure the payment of an installment note by executing a Security Agreement and Financing Statement transferring to the United States a security interest in the assets until the debt is discharged.

(c) *To whom payment is made.* Payment of a debt is made by check, draft, or money order payable to the United States Nuclear Regulatory Commission, and mailed or delivered to the Division of Accounting, Office of the Controller, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, unless payment is—

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(1) Made pursuant to arrangements with GAO or DOJ;

(2) Ordered by a Court of the United States; or

(3) Otherwise directed in any other part of this chapter.

§ 15.37 Interest and late payment charges.

(a) Interest begins to accrue from the due date specified in the initial written demand unless a different date is specified in a statute, regulation, or contract.

(b) If a debt, initially asserted by the NRC after the effective date of this Part, is not paid in full on or before the due date, the NRC shall assess a late payment charge based upon the prevailing rate of interest (updated quarterly) required by the Treasury Fiscal Requirements Manual (I TFRM 6-8000), unless a different rate is prescribed by statute, regulation, or contract. This rate reflects the short-term value of funds to the Treasury Department and is publicized by the Treasury Department in the Federal Register. A late payment charge is assessed for each full or partial 30-day period after the due date. Any partial payment is applied first to the payment of accrued late payment charges and then to principal (in accordance with the so-called "U.S. Rule"), unless a different rule is prescribed by statute, regulation or contract.

(c) When arrangements are made to pay a debt in installments over a period of time, the NRC shall charge interest at the rate prescribed by the Treasury Department in its current monthly "Schedule of Certified Interest Rates With Range of Maturities" for a similar period of time. Installment payments are applied first to the payment of accrued interest and then to principal, unless a different rule is prescribed by statute, regulation, or contract. Interest is calculated on a daily (365 days per year) basis and applied to the unpaid balance.

(d) The NRC may waive either the imposition or collection of interest on an installment payment or a late payment charge if the amount is negligible in relation to the cost of billing and collecting the amount, or if it is in the best interests of the Government to do so.

§ 15.39 Bankruptcy claims.

When the NRC receives information that a debtor has filed a petition in bankruptcy or is the subject of a bankruptcy proceeding, it shall furnish information concerning the debt owed the United States to the appropriate United States Attorney to permit the filing of a claim.

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Subpart C—Compromise of a Claim

§ 15.41 When a claim may be compromised.

The NRC may compromise a claim not in excess of the monetary limitation if it has not been referred for litigation to the GAO or the DOJ. Only the Comptroller General or designee may effect the compromise of a claim that arises out of an exception made by the GAO in the account of an accountable officer, including a claim against the payee, prior to its referral by GAO for litigation.

§ 15.43 Reasons for compromising a claim.

A claim may be compromised for one or more of the reasons set forth below:

(a) The full amount cannot be collected because—

(1) The debtor is unable to pay the full amount within a reasonable time; or

(2) The debtor refuses to pay the claim in full and the Government is unable to enforce collection in full within a reasonable time by enforced collection proceedings.

(b) There is a real doubt concerning the Government's ability to prove its case in Court for the full amount claimed either because of the legal issues involved or a bona fide dispute as to the facts.

(c) The cost of collecting the claim is likely to exceed the difference between the proposed compromise amount and the full amount of the claim.

(d) The debtor's inability to pay, the Government's ability to enforce collection, and the amounts which are acceptable in compromise shall be determined in accordance with the Federal Claims Collection Standards, 4 CFR Part 103. Compromises payable in installments are discouraged, but, if necessary, shall provide that in the event of default—

(1) The entire balance of the debt becomes immediately due and payable; and

(2) The Government has the right to enforce any security interest.

§ 15.45 Restrictions on the compromise of a claim.

(a) The NRC may not accept a percentage of a debtor's profits or stock in a debtor corporation in compromise of a claim. In negotiating a compromise with a business concern, consideration is given to requiring a waiver of the tax-loss-carry-forward and tax-loss-carry-back rights of the debtor.

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(b) If two or more debtors are jointly and severally liable, collection action is not withheld against one debtor until the other or others pay their proportionate share. The amount of a compromise with one debtor is not considered a precedent or as morally binding in determining the amount which will be required from other debtors jointly and severally liable on the claim.

§ 15.47 Finality of a compromise.

An offer of compromise must be in writing and signed by the debtor. An offer of compromise which is accepted by the NRC is final and conclusive on the debtor and on all officials, agencies, and courts of the United States, unless obtained by fraud, misrepresentation, the presentation of a false claim, or mutual mistake of fact.

Subpart D—Suspension or Termination of Collection Action

§ 15.51 When collection action may be suspended or terminated.

The NRC may suspend or terminate collection action on a claim not in excess of the monetary limitation if it has not been referred for litigation to the GAO or the DOJ.

§ 15.53 Reasons for suspending collection action.

Collection action may be suspended temporarily—

(a) When the debtor cannot be located after diligent efforts and there is reason to believe that future collection action may be sufficiently productive to justify periodic review and action on the claim considering the size of the claim and the amount which may be realized on it; or

(b) When the debtor owns no substantial equity in realty and is unable to make payments on the Government's claim or effect a compromise on it at the time but the debtor's future prospects justify retention of the claim for periodic review and action and—

(1) The applicable statute of limitations has been tolled or started anew; or

(2) Future collection can be effected by offset notwithstanding the statute of limitations.

§ 15.55 Reasons for terminating collection action.

Collection action may be terminated—

(a) When it becomes clear that the Government cannot collect or enforce collection of any significant sum from the debtor having due regard for the judicial remedies available to the Government, the debtor's future financial prospects, and the exemptions available to the debtor under State and Federal law;

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(b) When the debtor cannot be located, there is no security remaining to be liquidated, the applicable statute of limitations has run, and the prospects of collecting by offset notwithstanding the bar of the statute of limitations is too remote to justify retention of the claim; or

(c) When it is likely that the cost of collection action will exceed the amount recoverable.

§ 15.57 Termination of collection action.

Collection action shall be terminated—

(a) Whenever it is determined that the claim is legally without merit; or

(b) When it is determined that the evidence necessary to prove the claim cannot be produced or the necessary witnesses are unavailable and efforts to induce voluntary payments have been unavailing.

§ 15.59 Transfer of a claim.

The NRC may transfer a claim to the GAO for advice when there is doubt whether collection action should be suspended or terminated.

Subpart E—Referral of a Claim

§ 15.61 Prompt referral.

(a) A claim which requires enforced collection action is referred to a private collection agency, to the GAO, or to the DOJ for litigation. A referral is made as early as possible consistent with aggressive collection action and in any event well within the time required to bring a timely suit against the debtor.

(b) The NRC may refer a claim to the GAO or the DOJ even though the termination of collection activity might otherwise be given consideration under § 15.55(a) or (c) if—

(1) A significant enforcement policy is involved in reducing a statutory penalty or forfeiture to judgment; or

(2) Recovery of a judgment is a prerequisite to the imposition of administrative sanctions, such as suspension or revocation of a license or the privilege of participating in a Government sponsored program.

§ 15.63 Referral of a claim to private agencies for collection.

The NRC may contract with one or more private agencies to supplement, but not replace, the NRC basic collection program. The NRC retains the authority to resolve disputes, compromise claims, terminate collection action, and initiate enforced collection through litigation.

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§ 15.65 Referral of a compromise offer.

The NRC may refer a debtor's firm written offer of compromise which is substantial in amount to the GAO or to the DOJ if the NRC is uncertain whether the offer should be accepted.

§ 15.67 Referral to the Department of Justice.

(a) A claim of less than $600, exclusive of interest, is not referred for litigation unless—

(1) Referral is important to a significant enforcement policy; or

(2) The debtor not only has the clear ability to pay the claim but the Government can effectively enforce payment.

(b) A claim on which the NRC holds a judgment is referred to the DOJ for further action if renewal of the judgment lien or enforced collection proceedings are justified under the criteria discussed in this part.

PART 15

DEBT COLLECTION PROCEDURES

STATEMENTS OF CONSIDERATION

47 FR 7615
Published 2/22/82
Effective 3/24/82

10 CFR Part 15

Debt Collection Procedures

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations by adding a new Part which establishes the procedures that NRC will follow to collect debts which are owed to it. The procedures are based upon the Federal Claims Collection Standards issued by the General Accounting Office (GAO) and the U.S. Department of Justice (DOJ), as amended on July 31, 1981. The Federal Claims Collection Act provides that these precedures be issued as regulations. The procedures will enable the NRC to improve its collection of debts.

EFFECTIVE DATE: March 24, 1982.

FOR FURTHER INFORMATION CONTACT: Graham D. Johnson, Deputy Director, Division of Accounting, Office of the Controller, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, (Telephone 301-492-7535).

SUPPLEMENTARY INFORMATION:

Background

On September 23, 1981, the Nuclear Regulatory Commission published a proposed rule (46 FR 46960-46964) inviting comments for 45 days ending November 9, 1981.

Recent studies by the Executive Branch Debt Collection Project and the GAO reveal that more than $25 billion of the $175 billion in debts owed to the United States are either delinquent or in default. The President directed in the 1982 Budget Revisions that the collection of amounts owed to the Government be improved. The Supplemental Appropriations and Rescission Act, 1980 (Pub. L. 96-304), requires agencies covered by the Act, including the NRC, to improve the collection of overdue debts owed to the United States and to bill interest on delinquent debts. This part improves NRC's collection of debts by—

(a) Informing debtors that NRC's collection procedures are based upon the Federal Claims Collection Standards;

(b) Specifying the content of progressively stronger demand letters;

(c) Informing debtors that late payment charges are added if debts are not paid on the due date;

(d) Advising debtors in certain instances to provide affidavits, cancelled checks, or other evidence to support assertions that a debt is not owed, the debt is less than the amount claimed, or the debtor is unable to pay in full or in installments;

(e) Requiring payments in installments to include interest and, if appropriate, to be secured;

(f) Giving debtors the right to an interview and the right to notice of an offset;

(g) Giving debtors the opportunity for a hearing if issues of credibility and veracity are involved; and

(h) Referring debts for collection by a private agency.

This Part applies to the collection of a debt initially asserted by the NRC after March 24,1982.

Response to Comments

In response to the comments received during the comment period, the NRC has amended the proposed rule.

One comment indicated that § 15.29 of the proposed rule could be construed as allowing suspension or revocation of any licensed activity under any circumstances for non-payment of any ordinary fee, and, if so construed, § 15.29 would be inconsistent with 4 CFR 102.8. The commenter requested that § 15.29 be reworded to provide only that a license may be withheld until the prescribed fee for that license has been paid. In response, §§ 15.21(b)(3)(iii) and 15.29 have been reworded to limit a suspension or revocation to the license involved in the non-payment of a debt. However, in the case of any inexcusable, prolonged or repeated failure of a debtor to pay a debt, the NRC may suspend or revoke licenses unrelated to the debt. In either situation, the suspension or revocation would not occur until after the debtor has had an opportunity to respond to an order to show cause.

Another comment indicated that § 15.37 of the proposed rule could be construed to allow the imposition of late payment charges on a debt initially asserted by the NRC before the effective date of the rule. To negate such a possibility, § 15.37 had been amended to limit its application to debts initially asserted after the effective date of the final rule.

Regulatory Impact. The NRC has determined that this rule does not impose unnecessary burdens on the economy or on individuals. The rule sets out the procedures that NRC uses in collecting debts which are owed the NRC. The procedures, based on the Federal Claims Collection Standards, will improve NRC's debt collection efforts while providing due process protections for the debtor.

Environmental Impact Statement. This rule does not significantly affect the environment. An environmental impact statement is not required under the National Environmental Policy Act of 1969.

Paperwork Reduction Act. This rule contains no new reporting and recordkeeping requirements and therefore is not subject to review by the Office of Management and Budget under the Paperwork Reduction Act, Pub. L. 96.511.

Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Commission certifies that this rule does not have a significant economic impact on a substantial number of small entities. As a result, a regulatory flexibility analysis has not been prepared. Interest and late payment charges imposed on a small entity will ordinarily not exceed $100 per year. This rule affects small entities billed for byproduct material inspection fees established under 10 CFR 170.32, Category 3, and for Freedom of Information Act computer tapes, and other reproduction costs. About 1600 billings are issued annually to small entities including physicians in private practice, small hospitals, universities, small consulting firms, public interest groups and other entities involved with radiography and research. Total annual billings to any one small entity are less than $1,000. Past experience shows that 98 to 99% of billings are paid within 120 days after the billing date. The late payment charges imposed on a small entity which pays the debt of $1,000 120 days after the billing date will be $40.47 assuming a current Treasury annual interest rate of 16.19%.

This rule allows a small entity to pay a debt on an installment basis if it is unable to pay a debt in full prior to the due date (ordinarily 30 days after billing date). Such an arrangement requires the payment of interest on the unpaid debt. The annual interest charges imposed on a small entity will be less than $100 assuming maximum billing of $1,000 paid in 12 monthly installments of less than $100 per month and an annual interest rate of 16%. To date no small entities have requested payment of a debt on an installment basis.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, the Federal Claims Collection Act of 1966 (31 U.S.C. 952) and section 553 of Title 5 of the United States Code, notice is hereby given that the NRC is adding a new Part 15 to 10 CFR Chapter 1.

PART 19

NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS; INSPECTIONS

Sec.
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19.30 Violations.
19.31 Application for exemptions.
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Authority: Secs. 53, 63, 81, 103, 104, 161, 186, 68 Stat. 930, 933, 935, 936, 937, 948, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2073, 2093, 2111, 2133, 2134, 2201, 2236, 2282); sec. 201, 88 Stat. 1242, as amended by Pub. L. 94–79, 89 Stat. 413 (42 U.S.C. 5841). Pub. L. 95–601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 19.11(a), (c), (d), and (e) and 19.12 are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§ 19.13 and 19.14(a) are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

§ 19.1 Purpose.

The regulations in this part establish requirements for notices, instructions, and reports by licensees to individuals participating in licensed activities, and options available to such individuals in connection with Commission inspections of licensees to ascertain compliance with the provisions of the Atomic Energy Act of 1954, as amended, Title II of the Energy Reorganization Act of 1974, and regulations, orders, and licenses thereunder regarding radiological working conditions.

40 FR 8774

§ 19.2 Scope.

The regulations in this part appy to all persons who receive, possess, use, or transfer material licensed by the Nuclear Regulatory Commission pursuant to the regulations in Parts 30 through 35,40,60,61,70 or 72 of this chapter, including persons licensed to operate a production or utilization facility pursuant to Part 50 of this chapter and persons licensed to possess power reactor spent fuel in an independent spent fuel storage installation (ISFSI) pursuant to Part 72 of this chapter.

47 FR 57446

§ 19.3 Definitions.

As used in this part:

(a) "Act" means the Atomic Energy Act of 1954, (68 Stat. 919) including any amendments thereto;

(b) "Commission" means the United States Nuclear Regulatory Commission;

(c) "Worker" means an individual engaged in activities licensed by the Commission and controlled by a licensee, but does not include the licensee.

38 FR 22217

(d) "License" means a license issued under the regulations in Parts 30 through 35,40,60,61,70 or 72 of this chapter, including licenses to operate a production or utilization facility pursuant to Part 50 of this chapter and licenses to possess power reactor spent fuel in an independent spent fuel storage installation (ISFSI) pursuant to Part 72 of this chapter. "Licensee" means the holder of such a license.

47 FR 57446

(e) "Restricted area" means any area access to which is controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials. "Restricted area" shall not include any areas used as residential quarters, although a separate room or rooms in a residential building may be set apart as a restricted area.

§ 19.4 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

38 FR 22217

§ 19.5 Communications.

Except where otherwise specified in this part, all communications and reports concerning the regulations in this part should be addressed to the Director, Office of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Communications, reports, and applications may be delivered in person at the Commission's offices at 1717 H Street, NW., Washington, D.C.; or at 7920 Norfolk Avenue, Bethesda, Maryland.

40 FR 8774

§ 19.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). OMB has approved the information collection requirements contained in this part under control number 3150–0044.

(b) The approved information collection requirements contained in this part appear in § 19.13.

49 FR 19623

§ 19.11 Posting of notices to workers.

(a) Each licensee shall post current copies of the following documents: (1) The regulations in this part and in Part 20 of this chapter; (2) the license, license conditions, or documents incorporated into a license by reference, and amendments thereto; (3) the operating procedures applicable to licensed activities; (4) any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to Subpart B of Part 2 of this chapter, and any response from the licensee.

(b) If posting of a document specified in paragraph (a) (1), (2) or (3) of this section is not practicable, the licensee may post a notice which describes the document and states where it may be examined.

38 FR 22217

(c) Each licensee and applicant shall post Form NRC–3, (Revision 6–82 or later) "Notice to Employees," as required by Parts 30, 40, 50, 60, 70, 72, and 150 of this chapter.

47 FR 30452

NOTE: Copies of Form NRC-3 may be obtained by writing to the Director of the appropriate U.S. Nuclear Regulatory Commission Inspection and Enforcement Regional Office listed in Appendix "D", Part 20 of this chapter, or the Director, Office of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(d) Documents, notices, or forms posted pursuant to this section shall appear in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

(e) Commission documents posted pursuant to paragraph (a)(4) of this section shall be posted within 2 working days after receipt of the documents from the Commission; the licensee's response, if any, shall be posted within 2 working days after dispatch by the licensee. Such documents shall remain posted for a minimum of 5 working days or until action correcting the violation has been completed, whichever is later.

38 FR 22217

§ 19.12 Instructions to workers.

All individuals working in or frequenting any portion of a restricted area shall be kept informed of the storage, transfer, or use of radioactive materials or of radiation in such portions of the restricted area; shall be instructed in the health protection problems associated with exposure to such radioactive materials or radiation, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed; shall be instructed in, and instructed to observe, to the extent within the worker's control, the applicable provisions of Commission regulations and licenses for the protection of personnel from exposures to radiation or radioactive materials occurring in such areas; shall be instructed of their responsibility to report promptly to the licensee any condition which may lead to or cause a violation of Commission regulations and licenses or unnecessary exposure to radiation or to radioactive material; shall be instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and shall be advised as to the radiation exposure reports which workers may request pursuant to § 19.13. The extent of these instructions shall be commensurate with potential radiological health protection problems in the restricted area.

§ 19.13 Notifications and reports to individuals.

38 FR 22217 (a) Radiation exposure data for an individual, and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual, shall be reported to the individual as specified in this section. The information reported shall include data and results obtained pursuant to Commission regulations, orders or license conditions, as shown in records maintained by the licensee pursuant to Commission regulations. Each notification and report shall: be in writing; include appropriate identifying data such as the name of the licensee, the name of the individual, the individual's social security number; include the individual's exposure information; and contain the following statement:

> This report is furnished to you under the provisions of the Nuclear Regulatory Commission regulation 10 CFR Part 19. You should preserve this report for further reference

(b) At the request of any worker, each licensee shall advise such worker annually of the worker's exposure to radiation or radioactive material as shown in records maintained by the licensee pursuant to § 20.401(a) and (c).

(c) At the request of a worker formerly engaged in licensed activities controlled by the licensee, each licensee shall furnish to the worker a report of the worker's exposure to radiation or radioactive material. Such report shall be furnished within 30 days from the time the request is made, or within 30 days after the exposure of the individual has been determined by the licensee, whichever is later; shall cover, within the period of time specified in the request, each calendar quarter in which the worker's activities involved exposure to radiation from radioactive materials licensed by the Commission; and shall include the dates and locations of licensed activities in which the worker participated during this period.

(d) When a licensee is required pursuant to § 20.405 or § 20.408 of this chapter to report to the Commission any exposure of an individual to radiation or radioactive material the licensee shall also provide the individual a report on his exposure data included therein. Such report shall be transmitted at a time not later than the transmittal to the Commission.

44 FR 32352 (e) At the request of a worker who is terminating employment in a given calendar quarter with the licensee in work involving radiation dose, or of a worker who, while employed by another person, is terminating assignment to work involving radiation dose in the licensee's facility in that calendar quarter, each licensee shall provide to each such worker, or to the worker's designee, at termination, a written report regarding the radiation dose received by that worker from operations of the licensee during that specifically identified calendar quarter or fraction thereof, or provide a written estimate of that dose if the finally determined personnel monitoring results are not available at that time. Estimated doses shall be clearly indicated as such.

§ 19.14 Presence of representatives of licensees and workers during inspections.

38 FR 22217 (a) Each licensee shall afford to the Commission at all reasonable times opportunity to inspect materials, activities, facilities, premises, and records pursuant to the regulations in this chapter.

(b) During an inspection, Commission inspectors may consult privately with workers as specified in § 19.15. The licensee or licensee's representative may accompany Commission inspectors during other phases of an inspection.

(c) If, at the time of inspection, an individual has been authorized by the workers to represent them during Commission inspections, the licensee shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

(d) Each workers' representative shall be routinely engaged in licensed activities under control of the licensee and shall have received instructions as specified in § 19.12.

(e) Different representatives of licensees and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the inspectors.

(f) With the approval of the licensee and the workers' representative an individual who is not routinely engaged in licensed activities under control of the license, for example, a consultant to the licensee or to the workers' representative, shall be afforded the opportunity to accompany Commission inspectors during the inspection of physical working conditions.

(g) Notwithstanding the other provisions of this section, Commission inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to areas containing information classified by an agency of the U.S. Government in the interest of national security, an individual who accompanies an inspector may have access to such information only if authorized to do so. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee to enter that area.

§ 19.15 Consultation with workers during inspections.

(a) Commission inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of Commission regulations and licenses to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

38 FR 22217 (b) During the course of an inspection any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which he has reason to believe may have contributed to or caused any violation of the act, the regulations in this chapter, or license condition, or any unnecessary exposure of an individual to radiation from licensed radioactive material under the licensee's control. Any such notice in writing shall comply with the requirements of § 19.16(a).

(c) The provisions of paragraph (b) of this section shall not be interpreted as authorization to disregard instructions pursuant to § 19.12.

§ 19.16 Requests by workers for inspections.

(a) Any worker or representative of workers who believes that a violation of the Act, the regulations in this chapter, or license conditions exists or has occurred in license activities with regard to radiological working conditions in which the worker is engaged, may request an inspection by giving notice of the alleged violation to the Director of Inspection and Enforcement, to the Director of the appropriate Commission Regional Office, or to Commission inspectors. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of workers. A copy shall be provided the licensee by the Director of Inspection and Enforcement, Regional Office Director, or the inspector no later than at the time of inspection except that, upon the request of the worker giving such notice, his name and the name of individuals referred to therein shall not appear in such copy or on any record published, released, or made available by the Commission, except for good cause shown.

(b) If, upon receipt of such notice, the Director of Inspection and Enforcement or Regional Office Director determines that the complaint meets the requirements set forth in paragraph (a) of this section, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, he shall cause an inspection to be made as soon as practicable, to determine if such alleged violation exists or has occurred. Inspections pursuant to this section need not be limited to matters referred to in the complaint.

§ 19.17 Inspections not warranted; informal review.

(a) If the Director of Inspection and Enforcement or of the appropriate Regional Office determines, with respect to a complaint under § 19.16, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, he shall notify the complainant in writing of such determination. The complainant may obtain review of such determination by submitting a written statement of position with the Executive Director for Operations, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, who will provide the licensee with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The licensee may submit an opposing written statement of position with the Executive Director for Operations who will provide the complainant with a copy of such statement by certified mail. Upon the request of the complainant, the Executive Director for Operations or his designee may hold an informal conference in which the complainant and the licensee may orally present their views. An informal conference may also be held at the request of the licensee, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written and oral views presented, the Executive Director for Operations shall affirm, modify, or reverse the determination of the Director of Inspection and Enforcement or of the appropriate Regional Office and furnish the complainant and the licensee a written notification of his decision and the reason therefor.

(b) If the Director of Inspection and Enforcement or of the appropriate Regional Office determines that an inspection is not warranted because the requirements of § 19.16(a) have not been met, he shall notify the complainant in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of § 19.16(a).

38 FR 22217

§ 19.20 Employee protection.

Employment discrimination by a licensee or a contractor or subcontractor of a licensee against an employee for engaging in protected activities under this part or Parts 30, 40, 50, 60, 70, 72, or 150 of this chapter is prohibited.

47 FR 30452

§ 19.30 Violations.

An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or Title II of the Energy Reorganization Act of 1974, or any regulation or order issued thereunder.

40 FR 8774

A court order may be obtained for the payment of a civil penalty imposed pursuant to section 234 of the Act for violation of section 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Act or any rule, regulation, or order issued thereunder, or any term, condition or limitation of any license issued thereunder, or for any violation for which a license may be revoked under section 186 of the Act. Any person who willfully violates any provision of the Act or any regulation or order issued thereunder may be guilty of a crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law.

§ 19.31 Application for exemptions.

The Commission may, upon application by any licensee or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not result in undue hazard to life or property.

38 FR 22217

§ 19.32 Discrimination prohibited.

No person shall on the ground of sex be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity licensed by the Nuclear Regulatory Commission. This provision will be enforced through agency provisions and rules similar to those already established, with respect to racial and other discrimination, under title VI of the Civil Rights Act of 1964. This remedy is not exclusive, however, and will not prejudice or cut off any other legal remedies available to a discriminatee.

40 FR 8774

PART 19

NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS; INSPECTIONS

PROPOSED RULE MAKING

40 FR 799
Published 1/3/75
Comment Period expires 3/5/75

Radiation Protection; Implementation of NCRP Recommendations for Lower Radiation Exposure Levels for Fertile Women

See Part 20 Proposed Rule Making.

50 FR 13797
Published 4/8/85
Comment period expires 7/8/85

Licenses and Radiation Safety Requirements for Well-Logging Operations

See Part 39 Proposed Rule Making

UNITED STATES NUCLEAR REGULATORY COMMISSION

RULES and REGULATIONS

TITLE 10, CHAPTER 1, CODE OF FEDERAL REGULATIONS—ENERGY

PART 19

NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS; INSPECTIONS

STATEMENTS OF CONSIDERATION

38 FR 22217
Published 8/17/73
Effective 9/17/73

The Atomic Energy Commission has adopted a new regulation, 10 CFR Part 19, Notices, Instructions and Reports to Workers; Inspections, which includes certain provisions for the options of workers engaged in licensed activities concerning Commission inspections. These provisions are comparable with those provided by the Department of Labor for inspections pursuant to the Occupational Safety and Health Act of 1970 (OSHA), as set out in 29 CFR Part 1903. Several requirements from 10 CFR Part 20 regarding information that licensees must provide for these workers are included in Part 19.

The basic purpose of the new Part 19 is to provide options to workers concerning inspections of working conditions regulated by the Commission comparable to those afforded for working conditions regulated by the Department of Labor.

The Commission published a notice of proposed rulemaking in the FEDERAL REGISTER on January 4, 1973 (38 FR 802) that included the proposed Part 19. Interested persons were invited to submit written comments or suggestions for consideration in connection with the proposed amendments within 45 days after publication of the notice of proposed rule-making in the FEDERAL REGISTER.

After consideration of the comments received and other factors involved, the Commission has adopted the proposed new part and associated amendments to Part 20 published for comment, with certain modifications and editorial changes, and has amended 10 CFR Parts 31, 34, 35, 40, 70, 115 and 150, to clarify the applicability of Part 19. The more important changes made in Part 19 and the amendments based largely on these comments, are as follows:

(1) In many cases, the licensee may not be the employer of the individual workers protected by the amendments. Since it is the responsibility of the licensee rather than the individual's employer to control radiological working conditions, the terms "employer" and "employee" have been eliminated. The terms "licensee" and "worker" or "individual" as appropriate are used instead.

(2) Licensees frequently conduct licensed activities at two or more locations often involving different kinds of work. It has been made clear that the intent of the posting requirements in the proposed § 19.11 was to make the relevant documents accesible to workers involved in the licensed activities at the location to which the documents, e.g., notices of violation, apply.

(3) It has been clarified that the requirement in § 19.11 for posting notices of violations, notices of proposed imposition of civil penalty, or orders issued pursuant to Subpart B of Part 2 of this chapter, applies only to documents relevant to radiological working conditions.

(4) In many cases, the documents required to be posted by the provisions of § 19.11 are complex, bulky, and of little interest to any but the workers engaged in the particular licensed activity. If adequate accessibility of these documents to workers is assured, it is considered acceptable instead to post a notice describing such documents, stating where they may be examined.

(5) Because of the time required to disseminate and post a notice of violation, proposed imposition of civil penalty, or order issued by the Commission, and to prepare a preliminary response if desired, the time within which documents are required to be posted has been changed in § 19.11 from 24 hours to 2 working days. Similarly, to take into account prompt corrective action, the time required for the documents to remain posted is changed from 10 working days (or until correction, whichever is later) to 5 working days (or until correction, whichever is later).

(6) Section 19.15 permits the worker to bring occupational radiological protection matters privately to the attention of the inspector; § 19.16 permits the worker to notify the Commission in writing about working conditions he believes are in violation of the Act, the regulations, or license conditions; on the other hand, § 19.12 requires the licensee to instruct the worker to report promptly to the licensee certain matters regarding working conditions. The interests of worker safety are best served in matters concerning working conditions if supervisors, who can act promptly to correct undesirable conditions, are notified promptly. It is the intent of this regulation to encourage the worker to notify the licensee of possibly undesirable conditions prior to his notifying the Commission, thus avoiding unnecessary delays in corrective action. The point is clarified.

In addition, a number of other minor and editorial changes have been made that reflect written comments received.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of title 5 of the United States Code, the following new Part 19 of Title 10, Chapter I, Code of Federal Regulations is published as a document subject to codification, to be effective on September 17, 1973.

40 FR 8774
Published 3/3/75
Effective 3/3/75

Energy Reorganization Act; Revision to Chapter 1 to Reflect Organizational and Procedural Changes

See Part 2 Statements of Consideration.

44 FR 32349
Published 6/6/79
Effective 8/20/79

Control of Radiation Exposure to Transient Workers

See Part 20 Statements of Consideration.

46 FR 58281
Published 12/1/81
Effective 12/1/81

Licensing Requirements for the Storage of Spent Fuel in an Independent Spent Fuel Storage Installation; Minor Clarifying and Conforming Amendments

See Part 72 Statements of Consideration

47 FR 30452
Published 7/14/82
Effective 10/12/82

10 CFR Parts 19, 30, 40, 50, 60, 70, 72, and 150

Protection of Employees Who Provide Information

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The NRC is amending its regulations in regard to job protection for employees who provide information to the Commission. These amendments emphasize to employers—that is, licensees, permittees, applicants, and their contractors and subcontractors—that termination or other acts of job discrimination against employees who engage in activities furthering the purposes of the Atomic Energy Act and the Energy Reorganization Act is prohibited. In addition, these amendments will make the employee aware that if discrimination of this nature is believed to have occurred, a remedy is available through the Wage and Hour Division of the Department of Labor. To ensure that employees of licensees, permittees, and applicants are aware of these amendments, these organizations are required to post their premises with explanatory material related to the prohibition of discrimination and availability of a remedy in the event of discrimination.

EFFECTIVE DATE: October 12, 1982.

FOR FURTHER INFORMATION CONTACT: Mr. A. J. DiPalo, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. (301–443–5981).

SUPPLEMENTARY INFORMATION: On March 10, 1980, NRC published in the **Federal Register** (45 FR 15184) proposed amendments related to employee protection. Those proposed amendments were intended (1) to implement section 210, "Employee Protection," of the Energy Reorganization Act of 1974, 42 U.S.C. 5851, as amended, (2) to incorporate into the regulations the Commission's authority under Section 161 of the Atomic Energy Act of 1954, as amended, to investigate an alleged unlawful discrimination against an employee and to take appropriate action, and (3) to complement the Department of Labor's program that is related to this matter (29 CFR Part 24). Section 210 identifies specific acts of employees as protected activities and prohibits employers from discriminating against employees who engage in those activities, provides the Department of Labor with new authority to investigate an alleged act of such discrimination, and provides a remedy to the discrimination by means of an administrative proceeding in the Department of Labor.

Those proposed amendments would announce the statutory prohibition of discrimination of the type described in section 210 above, indicate the availability through the Department of Labor of a remedy for employees who believe they have been unlawfully discriminated against, and also require posting by specific types of licensees, permittees, and applicants of a revised NRC Form 3 that explains the prohibition and remedy. In addition, those amendments would delete 10 CFR 19.16(c) of the Commissions regulations, but at the same time amend Part 19 by the addition of a new § 19.20. This new section, when combined with proposed changes to Parts 30, 40, 50, 60, 70, and 72 of the regulations, would extend the current prohibition of unlawful discrimination against workers who provide information concerning radiological working conditions to NRC to include employees who provide information relating to radiological health protection matters and matters that could affect the public health and safety. The prohibition of unlawful discrimination also extends to information relating to antitrust matters and safeguard matters that could affect the common defense and security if these matters are considered in connection with an application for a license. The amendments continue the exemption from the requirement to post NRC Form 3 for most "general licensees," for example, those granted under § 40.25(e). This exemption is based on the nature of the licensed activity and therefore has not been granted to the general licensee carrier of special nuclear material (10 CFR 70.20(a)).

Comments on the Proposed Rule

The Commission received 26 letters commenting on the proposed rule. Copies of those letters and an analysis of the comments are available for public inspection and copying for a fee at the Commission's Public Document Room at 1717 H Street NW., Washington, D.C.

A number of commenters stated that the proposed rule would extend the NRC activities beyond the regulatory area of radiological working conditions that is applicable to all licensees. The commenters interpreted the rulemaking preamble as a Commission attempt to become involved in antitrust, safety, and security matters of all licensees. This was not the Commission's intent. Matters pertaining to radiological working conditions and radiological safety of all licensees are of concern to the Commission. However, antitrust and security matters are relevant only to certain types of licensees. For example, antitrust information is considered by the Commission only with respect to certain production and utilization facilities (primarily nuclear reactors). This rule is not intended to extend the Commission's involvement with antitrust or security matters to licensees with whom such matters are not presently considered. As noted earlier, the final rule involves the Commission in radiological safety aspects of all licensees (and their contractors and subcontractors) that are beyond the area of radiological working conditions. This involvement is appropriate since an individual fabricating a component that is destined for use in connection with a regulated facility or activity may be fabricating such component in a nonradiological work area but that individual may possess information that indicates the component, when installed at the regulated facility or activity, may contribute to a degradation of public health or safety. At times this information has not been readily available from those responsible for component fabrication, for example, licensees and their subcontractors. The Commission, to effectively fulfill its mandate, requires complete, factual, and current information concerning the regulated activities of its licensees. Employees are an important source of such information and should be encouraged to come forth with any items of potential significance to safety without fear of retribution from their employers. The purpose of the final rule is to ensure that employees are aware that employment discrimination for engaging in a protected activity, for example, contacting the Commission, is illegal and that a remedy exists through the Department of Labor. The organizations subject to the rule should understand that the Commission will not permit any interference with communications between the Commission's representatives and employees of such organization. In addition to redress being available to the individual employee, the Commission may, upon learning of an adverse finding against an employer by the Department of Labor, take enforcement action against the employer because the employer engaged in illegal discrimination.

Based on the comments received, the following substantive changes have been incorporated into the final rule:

(1) The definition of discrimination has been revised to more closely track the statutory language (see § 30.7(a)).[1]

(2) The statute expressly provides that an employee is not protected from actions taken by the employer when the employer's action is in response to the employee's deliberate action to violate the Atomic Energy Act of 1954, as amended, or the Energy Reorganization Act of 1974, as amended. This concept was not included in the proposed rule but has been incorporated in the final rule for completeness (see § 30.7(a)).

(3) The statement of available NRC enforcement actions that are derived from the Atomic Energy Act, as amended, (see § 30.7(c)) has been revised to more clearly state the policy of enforcement in the event of unlawful discrimination.

(4) A new § 30.7(d) has been added to clarify the fact that some actions taken by an employer that adversely affect an employee are not prohibited by the new regulation.

The final rule requires, in a manner similar to the proposed amendments, that the premises of licensees—including permit holders—and applicants be posted, e g., 10 CFR 50.7(e). In the course of construction of a nuclear facility an organization may transfer administrative control of a portion of its premises to a contractor or subcontractor, e g., an office or supply trailer or a large area for concrete construction. Such transfer does not eliminate the requirement for posting by the licensee, permit holder or applicant of those premises in a manner adequate to ensure that employees of a contractor or subcontractor are able to observe the posted information on the way to or from their place of work.

In developing the final rule the Commission considered including in its requirements that would, by one of various means, cause information related to employee protection to be posted on the premises of contractors and subcontractors of licensees—including permit holders—and applicants. Based on, among other things, the experience gained in the drafting and implementing of 10 CFR Part 21 the Commission has determined that contractors and subcontractors should be required to post NRC Form 3. Accordingly, the staff has underway a rulemaking proposing an amendment of 10 CFR 50.7(e) to require contractors and subcontractors to post NRC Form 3 on their premises.

Based on NRC staff comments, the Parts of Title 10 that are included in the rulemaking have been revised to delete Part 71, "Packaging of Radioactive Material for Transport and Transportation of Radioactive Material Under Certain Conditions," to add Part 60, "Disposal of High Level Radioactive Wastes in Geologic Repositories," and to add Part 72, "Licensing Requirements for the Storage of Spent Fuel in an Independent Spent Fuel Storage Installation (ISFSI)." Part 71 was deleted since all general licensees under Part 71 are also specific licensees under another Part, e.g., Part 50, and are, therefore, included in this rulemaking. Conforming amendments to Parts 60 and 72 are included in this final rulemaking to effectuate the Commission's intent that all specific licensees will have similar responsibilities under the Employee Protection amendments. Parts 60 and 72 were not included in the proposed rulemaking since they had not been codified at that time. Conforming amendments will be made to Part 61, "Licensing Requirements for Land Disposal of Radioactive Waste" when that proposed rule (46 FR 38081, July 24, 1981) becomes final.

A number of comments from licensees and their consultants stated that the proposed rule would allow the individuals to harass the employer with accusations that are false, frivolous, or unwarranted. To prevent this, it was recommended that either civil penalties be imposed on the individual that knowingly supplies false information or that compensation be provided to an employer to defray the cost of defending against the allegations. The Commission has rejected these comments since the statutory authority of the Commission under section 210 neither provides for penalties against individuals or for any reimbursement to an employer. Based on a review of allegations of employment discrimination complaints filed with DOL, it appears that at an early stage, DOL denies complaints that are without merit.

List of Subjects

10 CFR Part 19

Environmental protection, Nuclear materials, nuclear power plants and reactors, Occupational safety and health, Penalty, Radiation protection, Reporting requirements, Sex discrimination.

10 CFR Part 30

Byproduct material, Labeling, Nuclear materials, Packaging and containers, Penalty, Radiation protection, Reporting requirements, Scientific equipment.

10 CFR Part 40

Government contracts, Hazardous materials—transportation, Nuclear materials, Penalty, Reporting requirements, Source material, Uranium.

10 CFR Part 50

Antitrust, Classified information, Fire prevention, Intergovernmental relations, Nuclear power plants and reactors, Penalty, Radiation protection, Reactor siting criteria, Reporting requirements.

10 CFR Part 60

High-level waste, Nuclear power plants and reactors, Nuclear materials, Penalty, Reporting requirements, Waste treatment and disposal.

10 CFR Part 70

Hazardous materials—transportation, Nuclear materials, Packaging and containers, Penalty, Radiation protection, Reporting requirements.

10 CFR Part 72

Manpower training programs, Nuclear materials, Occupational safety and health, Reporting requirements, Security measures, Spent fuel.

10 CFR Part 150

Hazardous materials—transportation, Intergovernmental relations, Nuclear materials, Penalty, Reporting requirements, Security measures, Source material, Special nuclear material.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of title 5 of the United States Code, notice is hereby given that the following amendments to Title 10, Chapter I, Code of Federal Regulations, are published as a document subject to codification.

47 FR 57446
Published 12/27/82
Effective dates:
10 CFR 20.311 of Part 20 effective date is 12/27/83; 10 CFR Part 61 and all other changes effective 1/26/83.

Licensing Requirements for Land Disposal of Radioactive Waste

See Part 61 Statements of Consideration

49 FR 19623
Published 5/9/84
Effective 5/9/84

Information Collection Requirements; Display of OMB Control Numbers

See Part 0 Statements of Consideration

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[1] For simplification in the preamble, reference is made only to the changes to Part 30. Conforming changes have also been made to Parts 40, 50, 60, 70 and 72.

PART 20

STANDARDS FOR PROTECTION AGAINST RADIATION

PART 20—STANDARDS FOR PROTECTION AGAINST RADIATION

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Authority: Secs. 53, 63, 65, 81, 103, 104, 161, 68 Stat. 930, 933, 935, 936, 937, 948, as amended, (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201); secs. 201, as amended, 202, 206, Pub. L. 93–438, 88 Stat. 1242, 1244, 1246, Pub. L. 94–79, 89 Stat. 413 (42 U.S.C. 5841, 5842, 5846).

For the purposes of sec. 223, 68 Stat. 958, as amended, (42 U.S.C. 2273), §§ 20.101, 20.102, 20.103(a) (b), and (f), 20.104 (a) and (b), 20.105(b), 20.106(a), 20.201, 20.202(a), 20.205, 20.207, 20.301, 20.303, 20.304 and 20.305 are issued under sec. 161b, 68 Stat 948, as amended, (42 U.S.C. 2201(b)); and §§ 20.102, 20.103(e), 20.401–20.407, 20.408(b) and 20.409 are issued under sec. 161o, 68 Stat. 950, as amended, (42 U.S.C. 2201(o)).

GENERAL PROVISIONS

§ 20.1 Purpose.

(a) The regulations in this part establish standards for protection against radiation hazards arising out of activities under licenses issued by the Nuclear Regulatory Commission and are issued pursuant to the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974. 40 FR 8774

(b) The use of radioactive material or other sources of radiation not licensed by the Commission is not subject to the regulations in this part. However, it is the purpose of the regulations in this part to control the possession, use, and transfer of licensed material by any licensee in such a manner that the total dose to an individual (including exposures to licensed and unlicensed radioactive material and to other unlicensed sources of radiation, whether in the possession of the licensee or any other person, but not including exposures to radiation from natural background sources or medical diagnosis and therapy) does not exceed the standards of radiation protection prescribed in the regulations in this part. 44 FR 32352

(c) In accordance with recommendations of the Federal Radiation Council, approved by the President, persons engaged in activities under licenses issued by the Nuclear Regulatory Commission pursuant to the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974 should, in addition to complying with the requirements set forth in this part, make every reasonable effort to maintain radiation exposures, and releases of radioactive materials in effluents to unrestricted areas, as low as is reasonably achievable. The term "as low as is reasonably achievable" means as low as is reasonably achievable taking into account the state of technology, and the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to the utilization of atomic energy in the public interest. 40 FR 58847

§ 20.2 Scope.

The regulations in this part apply to all persons who receive, possess, use, or transfer material licensed pursuant to the regulations in Parts 30 through 35,40,60,61,70,or72 of this chapter, including persons licensed to operate a production or utilization facility pursuant to Part 50 of this chapter and persons licensed to possess power reactor spent fuel in an independent spent fuel storage installation (ISFSI) purusant to Part 72 of this chapter. 47 FR 57446

§ 20.3

§ 20.3 Definitions.

(a) As used in this part:

(1) "Act" means the Atomic Energy Act of 1954 (68 Stat. 919) including any amendments thereto;

(2) "Airborne radioactive material" means any radioactive material dispersed in the air in the form of dusts, fumes, mists, vapors, or gases;

(3) "Byproduct material" means any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material; 40 FR 8774

(4) "Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be such that no day is included in more than one calendar quarter or omitted from inclusion within a calendar quarter. No licensee shall change the method observed by him of determining calendar quarters except at the beginning of a calendar year. 40 FR 42557

(5) "Commission" means the Nuclear Regulatory Commission or its duly authorized representatives;

(6) "Government agency" means any executive department, commission, independent establishment, corporation, wholly or partly owned by the United States of America which is an instrumentality of the United States, or any board, bureau, division, service, office, officer, authority, administration, or other establishment in the executive branch of the Government;

(7) "Individual" means any human being;

(8) "Licensed material" means source material, special nuclear material, or by-product material received, possessed, used, or transferred under a general or specific license issued by the Commission pursuant to the regulations in this chapter.

25 FR 10914

(9) "License" means a license issued under the regulations in Parts 30 through 35,40,60,61,70 or 72 of this chapter. "Licensee" means the holder of such license;

47 FR 57446

(10) "Occupational dose" includes exposure of an individual to radiation (i) in a restricted area; or (ii) in the course of employment in which the individual's duties involve exposure to radiation, provided, that "occupational dose" shall not be deemed to include any exposure of an individual to radiation for the purpose of medical diagnosis or medical therapy of such individual.

25 FR 10914

(11) "Person" means: (i) Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, Government agency other than the Commission or the Department (except that the Department shall be considered a person within the meaning of the regulations in this part to the extent that its facilities and activities are subject to the licensing and related regulatory authority of the Commission pursuant to section 202 of the Energy Reorganization Act of 1974 (88 Stat. 1244)), any State, any foreign government or nation or any political subdivision of any such government or nation, or other entity; and (ii) any legal successor, representative, agent, or agency of the foregoing.

40 FR 8774

(12) "Radiation" means any or all of the following: alpha rays, beta rays, gamma rays, X-rays, neutrons, high-speed electrons, high-speed protons, and other atomic particles; but not sound or radio waves, or visible, infrared, or ultraviolet light;

25 FR 10914

(13) "Radioactive material" includes any such material whether or not subject to licensing control by the Commission;

(14) "Restricted area" means any area access to which is controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials. "Restricted area" shall not include any areas used as residental quarters, although a separate room or rooms in a residential building may be set apart as a restricted area;

25 FR 13952

(15) "Source material" means: (i) Uranium or thorium, or any combination thereof, in any physical or chemical form; or (ii) ores which contain by weight one-twentieth of one percent (0.05%) or more of (*a*) uranium, (*b*) thorium or (*c*) any combination thereof. Source material does not include special nuclear material.

27 FR 5905

(16) "Special nuclear material" means: (i) Plutonium, uranium 233, uranium enriched in the isotope 233 or in the isotope 235, and any other material which the Commission, pursuant to the provisions of section 51 of the act, determines to be special nuclear material, but does not include source material; or (ii) any material artificially enriched by any of the foregoing but does not include source material;

25 FR 10914

(17) "Unrestricted area" means any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials, and any area used for residential quarters.

25 FR 13952

(18) "Department" means the Department of Energy established by the Department of Energy Organization Act (Pub. L. 95-91, 91 Stat. 565, 42 U.S.C. 7101 *et seq.*) to the extent that the Department, or its duly authorized representatives, exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to sections 104 (b), (c) and (d) of the Energy Reorganization Act of 1974 (Pub. L. 93-438, 88 Stat. 1233 at 1237, 42 U.S.C. 5814) and retransferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Pub. L. 95-91, 91 Stat. 565 at 577-578, 42 U.S.C. 7151).

45 FR 14199

(19) "Termination" means the end of employment with the licensee or, in the case of individuals not employed by the licensee, the end of a work assignment in the licensee's restricted areas in a given calendar quarter, without expectation or specific scheduling of reentry into the licensee's restricted areas during the remainder of that calendar quarter.

44 FR 32352

(b) Definitions of certain other words and phrases as used in this part are set forth in other sections, including:

(1) "Airborne radioactivity area" defined in § 20.203;

(2) "Radiation area" and "high radiation area" defined in § 20.202;

(3) "Personnel monitoring equipment" defined in § 20.202;

(4) "Survey" defined in § 20.201;

(5) Units of measurement of dose (rad, rem) defined in § 20.4;

(6) Units of measurement of radioactivity defined in § 20.5.

§ 20.4 Units of radiation dose.

(a) "Dose," as used in this part, is the quantity of radiation absorbed, per unit of mass, by the body or by any portion of the body. When the regulations in this part specify a dose during a period of time, the dose means the total quantity of radiation absorbed, per unit of mass, by the body or by any portion of the body during such period of time. Several different units of dose are in current use. Definitions of units as used in this part are set forth in paragraphs (b) and (c) of this section.

(b) The rad, as used in this part, is a measure of the dose of any ionizing radiation to body tissues in terms of the energy absorbed per unit mass of the tissue. One rad is the dose corresponding to the absorption of 100 ergs per gram of tissue. (One millirad (mrad)=0.001 rad.)

(c) The rem, as used in this part, is a measure of the dose of any ionizing radiation to body tissues in terms of its estimated biological effect relative to a dose of one roentgen (r) of X-rays. (One millirem (mrem)=0.001 rem.) The relation of the rem to other dose units depends upon the biological effect under consideration and upon the conditions of irradiation. For the purpose of the regulations in this part, any of the following is considered to be equivalent to a dose of one rem:

(1) A dose of 1 r due to X– or gamma radiation;

(2) A dose of 1 rad due to X–, gamma, or beta radiation;

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(3) A dose of 0.1 rad due to neutrons or high energy protons;

(4) A dose of 0.05 rad due to particles heavier than protons and with sufficient energy to reach the lens of the eye; If it is more convenient to measure the neutron flux, or equivalent, than to determine the neutron dose in rads, as provided in paragraph (c)(3) of this section, one rem of neutron radiation may, for purposes of the regulations in this part, be assumed to be equivalent to 14 million neutrons per square centimeter incident upon the body; or, if there exists sufficient information to estimate with reasonable accuracy the approximate distribution in energy of the neutrons, the incident number of neutrons per square centimeter equivalent to one rem may be estimated from the following table:

NEUTRON FLUX DOSE EQUIVALENTS

Neutron energy (Mev)	Number of neutrons per square centimeter equivalent to a dose of 1 rem (neutrons/cm ^{2})	Average flux to delivery 100 millirem in 40 hours (neutrons/cm ^{2} sec.)
Thermal	970×10^6	670
0.0001	720×10^6	500
0.005	820×10^6	570
0.02	400×10^6	280
0.1	120×10^6	80
0.5	43×10^6	30
1.0	26×10^6	18
2.5	29×10^6	20
5.0	26×10^6	18
7.5	24×10^6	17
10	24×10^6	17
10 to 30	14×10^6	10

(d) For determining exposures to X or gamma rays up to 3 Mev, the dose limits specified in §§ 20.101 to 20.104, inclusive, may be assumed to be equivalent to the "air dose". For the purpose of this part "air dose" means that the dose is measured by a properly calibrated appropriate instrument in air at or near the body surface in the region of highest dosage rate.

§ 20.5 Units of radioactivity.

(a) Radioactivity is commonly, and for purposes of the regulations in this part shall be, measured in terms of disintegrations per unit time or in curies. One curie $= 3.7 \times 10^{10}$ disintegrations per second (dps) $= 2.2 \times 10^{12}$ disintegrations per minute (dpm). Commonly used submultiples of the curie are the millicurie and the microcurie:

(1) One millicurie (mCi) $^{1} = 0.001$ curie (Ci) $^{1} = 3.7 \times 10^{7}$ dps.

(2) One microcurie (μCi) $^{1} = 0.000001$ curie $= 3.7 \times 10^{4}$ dps.

(b) [Deleted 40 FR 50704.]

(c) [Deleted 39 FR 23990.]

§ 20.6 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

§ 20.7 Communications.

Except where otherwise specified in this part, all communications and reports concerning the regulations in this part should be addressed to the Executive Director for Operations, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Communications, reports, and applications may be delivered in person at the Commission's offices at 1717 H Street NW., Washington, D.C.; or at 7920 Norfolk Avenue, Bethesda, Maryland.

§ 20.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). OMB has approved the information collection requirements contained in this part under control number 3150–0014.

(b) The approved information collection requirements contained in this part appear in §§ 20.102, 20.103, 20.105, 20.106, 20.203, 20.205, 20.302, 20.311, 20.401, 20.402, 20.403, 20.405, 20.407, 20.408, and 20.409.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In §§ 20.101 and 20.102, Form NRC–4 is approved under control number 3150–0005.

(2) In § 20.401, Form NRC–5 is approved under control number 3150–0006.

PERMISSIBLE DOSES, LEVELS, AND CONCENTRATIONS

§ 20.101 Radiation dose standards for individuals in restricted areas.

(a) In accordance with the provisions of § 20.102(a), and except as provided in paragraph (b) of this section, no licensee shall possess, use, or transfer licensed material in such a manner as to cause any individual in a restricted area to receive in any period of one calendar quarter from radioactive material and other sources of radiation a total occupational dose in excess of the standards specified in the following table:

REMS PER CALENDAR QUARTER

1. Whole body, head and trunk; active blood-forming organs; lens of eyes, or gonads	1¼
2. Hands and forearms, feet and ankles	18¾
3. Skin of whole body	7½

(b) A licensee may permit an individual in a restricted area to receive a total occupational dose to the whole body greater than that permitted under paragraph (a) of this section, provided:

(1) During any calendar quarter the total occupational dose to the whole body shall not exceed 3 rems; and

(2) The dose to the whole body, when added to the accumulated occupational dose to the whole body, shall not exceed 5 (N-18) rems where "N" equals the individual's age in years at his last birthday; and

(3) The licensee has determined the individual's accumulated occupational dose to the whole body on Form NRC-4, or on a clear and legible record containing all the information required in that form; and has otherwise complied with the requirements of § 20.102. As used in paragraph (b), "Dose to the whole body" shall be deemed to include any dose to the whole body, gonads, active blood-forming organs, head and trunk, or lens of eye.

§ 20.102 Determination of prior dose.

(a) Each licensee shall require any individual, prior to first entry of the individual into the licensee's restricted area during each employment or work assignment under such circumstances that the individual will receive or is likely to receive in any period of one calendar quarter an occupational dose in excess of 25 percent of the applicable standards specified in § 20.101(a) and § 20.104(a), to disclose in a written, signed statement, either: (1) That the individual had no prior occupational dose during the current calendar quarter, or (2) the nature and amount of any occupational dose which the individual may have received during that specifically identified current calendar quarter from sources of radiation possessed or controlled by other persons. Each licensee shall maintain records of such statements until the Commission authorizes their disposition.

(b) Before permitting, pursuant to § 20.101(b), any individual in a restricted area to receive an occupational radiation dose in excess of the standards specified in § 20.101(a), each licensee shall:

(1) Obtain a certificate on Form NRC-4, or on a clear and legible record containing all the information required in that form, signed by the individual showing each period of time after the individual attained the age of 18 in which the individual received an occupational dose of radiation; and

(2) Calculate on Form NRC-4 in accordance with the instructions appearing therein, or on a clear and legible record containing all the information required in that form, the previously accumulated occupational dose received by the individual and the additional dose allowed for that individual under § 20.101(b).

(c)(1) In the preparation of Form NRC-4, or a clear and legible record containing all the information required in that form, the licensee shall make a reasonable effort to obtain reports of the individual's previously accumulated occupational dose. For each period for which the licensee obtains

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such reports, the licensee shall use the dose shown in the report in preparing the form. In any case where a licensee is unable to obtain reports of the individual's occupational dose for a previous complete calendar quarter, it shall be assumed that the individual has received the occupational dose specified in whichever of the following columns apply:

Part of body	Column 1—Assumed exposure in rems for calendar quarters prior to Jan. 1, 1961	Column 2—Assumed exposure in rems for calendar quarters beginning on or after Jan. 1, 1961
Whole body, gonads, active blood-forming organs, head and trunk, lens of eye	3¾	1¼

(2) The licensee shall retain and preserve records used in preparing Form NRC-4 until the Commission authorizes their disposition.

If calculation of the individual's accumulated occupational dose for all periods prior to January 1, 1961 yields a result higher than the applicable accumulated dose value for the individual as of that date, as specified in paragraph (b) of § 20.101, the excess may be disregarded.

§ 20.103 Exposure of individuals to concentrations of radioactive materials in air in restricted areas.

(a)(1) No licensee shall possess, use, or transfer licensed material in such a manner as to permit any individual in a restricted area to inhale a quantity of radioactive material in any period of one calendar quarter greater than the quantity which would result from inhalation for 40 hours per week for 13 weeks at uniform concentrations of radioactive material in air specified in Appendix B, Table I, Column 1.[1][2][3] If the radioactive material is of such form that intake by absorption through the skin is likely, individual exposures to radioactive material shall be controlled so that the uptake of radioactive material by any organ from either inhalation or absorption or both routes of intake[4][5] in any calendar quarter does not exceed that which would result from inhaling such radioactive material for 40 hours per week for 13 weeks at uniform concentrations specified in Appendix B, Table I, Column 1.

(2) No licensee shall possess, use, or transfer mixtures of U-234, U-235, and U-238 in soluble form in such a manner as to permit any individual in a restricted area to inhale a quantity of such material in excess of the intake limits specified in Appendix B, Table I, Column 1 of this part. If such soluble uranium is of a form such that absorption through the skin is likely, individual exposures to such material shall be controlled so that the uptake of such material by any organ from either inhalation or absorption or both routes of intake[4] does not exceed that which would result from inhaling such material at the limits specified in Appendix B, Table I, Column 1 and footnote 4 thereto.

(3) For purposes of determining compliance with the requirements of this section the licensee shall use suitable measurements of concentrations of radioactive materials in air for detecting and evaluating airborne radioactivity in restricted areas and in addition, as appropriate, shall use measurements of radioactivity in the body, measurements of radioactivity excreted from the body, or any combination of such measurements as may be necessary for timely detection and assessment of individual intakes of radioactivity by exposed individuals. It is assumed that an individual inhales radioactive material at the airborne concentration in which he is present unless he uses respiratory protective equipment pursuant to paragraph (c) of this section. When assessment of a particular individual's intake of radioactive material is necessary, intakes less than those which would result from inhalation for 2 hours in any one day or for 10 hours in any one week at uniform concentrations specified in Appendix B, Table I, Column 1 need not be included in such assessment, provided that for any assessment in excess of these amounts the entire amount is included.

(b)(1) The licensee shall, as a precautionary procedure, use process or other engineering controls, to the extent practicable, to limit concentrations of radioactive materials in air to levels below those which delimit an airborne radioactivity area as defined in § 20.203(d)(1)(ii).

(2) When it is impracticable to apply process or other engineering controls to limit concentrations of radioactive material in air below those defined in § 20.203(d)(1)(ii), other precautionary procedures, such as increased surveillance, limitation of working times, or provision of respiratory protective equipment, shall be used to maintain intake of radioactive material by any individual within any period of seven consecutive days as far below that intake of radioactive material which would result from inhalation of such material for 40 hours at the uniform concentrations specified in Appendix B, Table 1, Column 1 as is reasonably achievable. Whenever the intake of radioactive material by any individual exceeds this 40-hour control measure, the licensee shall make such evaluations and take such actions as are necessary to assure against recurrence. The licensee shall maintain records of such occurrences, evaluations, and actions taken in a clear and readily identifiable form suitable for summary review and evaluation.

(c) When respiratory protective equipment is used to limit the inhalation of airborne radioactive material pursuant to paragraph (b)(2) of this section, the licensee shall use equipment that is certified or had certification extended by the National Institute for Occupational Safety and Health/Mine Safety and Health Administration (NIOSH/MSHA). The licensee may make allowance for this use of respiratory protective equipment in estimating exposures of individuals to this material provided that:

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[1] Since the concentration specified for tritium oxide vapor assumes equal intakes by skin absorption and inhalation, the total intake permitted is twice that which would result from inhalation alone at the concentration specified for H 3 S in Appendix B, Table I, Column 1 for 40 hours per week for 13 weeks.

[2] For radon-222, the limiting quantity is that inhaled in a period of one calendar year. For radioactive materials designated "Sub" in the "Isotope" column of the table, the concentration value specified is based upon exposure to the material as an external radiation source. Individual exposures to these materials may be accounted for as part of the limitation on individual dose in § 20.101. These nuclides shall be subject to the precautionary procedures required by § 20.103(b)(1).

[3] Multiply the concentration values specified in Appendix B, Table I, Column 1, by 6.3×10^8 ml to obtain the quarterly quantity limit. Multiply the concentration value specified in Appendix B, Table I, Column 1, by 2.5×10^9 ml to obtain the annual quantity limit for Rn-222.

[4] Significant intake by ingestion or injection is presumed to occur only as a result of circumstances such as accident, inadvertence, poor procedure, or similar special conditions. Such intakes must be evaluated and accounted for by techniques and procedures as may be appropriate to the circumstances of the occurrence. Exposures so evaluated shall be included in determining whether the limitation on individual exposures in § 20.103(a)(1) has been exceeded.

[5] Regulatory guidance on assessment of individual intakes of radioactive material is given in Regulatory Guide 8.9, "Acceptable Concepts, Models, Equations and Assumptions for a Bioassay Program," single copies of which are available from the Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, upon written request.

(1) The licensee selects respiratory protective equipment that provides a protection factor greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in Appendix B, Table I, Column 1 of this part. The equipment so selected shall be used so that the average concentration of radioactive material in the air that is inhaled during any period of uninterrupted use in an airborne radioactivity area, on any day, by any individual using the equipment, does not exceed the values specified in Appendix B, Table I, Column 1 of this part. For the purposes of this paragraph, the concentration of radioactive material in the air that is inhaled when respirators are worn may be estimated by dividing the ambient concentration in air by the protection factor specified in Appendix A of this part. If the exposure is later found to be greater than estimated, the corrected value shall be used; if the exposure is later found to be less than estimated, the corrected value may be used.

47 FR 16162

(2) The licensee maintains and implements a respiratory protection program that includes, as a minimum: air sampling sufficient to identify the hazard, permit proper equipment selection and estimate exposures; surveys and bioassays as appropriate to evaluate actual exposures; written procedures regarding selection, fitting, and maintenance of respirators, and testing of respirators for operability immediately prior to each use; written procedures regarding supervision and training of personnel and issuance records; and determination by a physician prior to initial use of respirators, and at least every 12 months thereafter, that the individual user is physically able to use the respiratory protective equipment.

(3) A written policy statement on respirator usage shall be issued covering such things as: use of practicable engineering controls instead of respirators; routine, nonroutine, and emergency use of respirators; and periods of respirator use and relief from respirator use. The licensee shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other condition that might require such relief.

(4) The licensee uses equipment within limitations for type and mode of use and provides proper visual, communication, and other special capabilities (such as adequate skin protection) when needed.

(d) Unless otherwise authorized by the Commission, the licensee shall not assign protection factors in excess of those specified in Appendix A of this part in selecting and using respiratory protective equipment. The Commission may authorize a licensee to use higher protection factors on receipt of an application (1) describing the situation for which a need exists for higher protection factors, and (2) demonstrating that the respiratory protective equipment will provide these higher protection factors under the proposed conditions of use.

(e) Where equipment of a particular type has not been tested and certified, or had certification extended, by NIOSH/MSHA, or where there is no existing schedule for test and certification of certain equipment, the licensee shall not make allowance for this equipment without specific authorization by the Commission. An application for this authorization must include a demonstration by testing, or on the basis of reliable test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use.

(f) Only equipment that has been specifically certified or had certification extended for emergency use by NIOSH/MSHA shall be used as emergency devices.

47 FR 16162

(g) The licensee shall notify, in writing, the Director of the appropriate Nuclear Regulatory Commission Inspection and Enforcement Regional Office listed in Appendix D at least 30 days before the date that respiratory protective equipment is first used under the provisions of this section

§ 20.104 Exposure of minors.

(a) No licensee shall possess, use, or transfer licensed material in such a manner as to cause any individual within a restricted area who is under 18 years of age, to receive in any period of one calendar quarter from radioactive material and other sources of radiation in the licensee's possession a dose in excess of 10 percent of the limits specified in the table in paragraph (a) of § 20.101.

(b) No licensee shall possess, use or transfer licensed material in such a manner as to cause any individual within a restricted area, who is under 18 years of age to be exposed to airborne radioactive material possessed by the licensee in an average concentration in excess of the limits specified in Appendix B, Table II of this part. For purposes of this paragraph, concentrations may be averaged over periods not greater than a week.

25 FR 10914

(c) The provisions of §§ 20.103(b)(2) and 20.103(c) shall apply to exposures subject to paragraph (b) of this section except that the references in §§ 20.103(b)(2) and 20.103(c) to Appendix B, Table I, Column 1 shall be deemed to be references to Appendix B, Table II, Column 1.

41 FR 52302

§ 20.105 Permissible levels of radiation in unrestricted areas.

(a) There may be included in any application for a license or for amendment of a license proposed limits upon levels of radiation in unrestricted areas resulting from the applicant's possession or use of radioactive material and other sources of radiation. Such applications should include information as to anticipated average radiation levels and anticipated occupancy times for each unrestricted area involved. The Commission will approve the proposed limits if the applicant demonstrates that the proposed limits are not likely to cause any individual to receive a dose to the whole body in any period of one calendar year in excess of 0.5 rem.

(b) Except as authorized by the Commission pursuant to paragraph (a) of this section, no licensee shall possess, use or transfer licensed material in such a manner as to create in any unrestricted area from radioactive material and other sources of radiation in his possession:

(1) Radiation levels which, if an individual were continuously present in the area, could result in his receiving a dose in excess of two millirems in any one hour, or

(2) Radiation levels which, if an individual were continuously present in the area, could result in his receiving a dose in excess of 100 millirems in any seven consecutive days.

25 FR 10914

(c) In addition to other requirements of this part, licensees engaged in uranium fuel cycle operations subject to the provisions of 40 CFR Part 190, "Environmental Radiation Protection Standards for Nuclear Power Operations," shall comply with that part.

46 FR 18525

§ 20.106 Radioactivity in effluents to unrestricted areas.

(a) A licensee shall not possess, use, or transfer licensed material so as to release to an unrestricted area radioactive material in concentrations which exceed the limits specified in Appendix B, Table II of this part, except as authorized pursuant to § 20.302 or paragraph (b) of this section. For purposes of this section concentrations may be averaged over a period not greater than one year.

29 FR 14434

(b) An application for a license or amendment may include proposed limits higher than those specified in paragraph (a) of this section. The Commission will approve the proposed limits if the applicant demonstrates:

(1) That the applicant has made a reasonable effort to minimize the radioactivity contained in effluents to unrestricted areas; and

(2) That it is not likely that radioactive material discharged in the effluent would result in the exposure of an individual to concentrations of radioactive material in air or water exceeding the limits specified in Appendix B, Table II of this part.

(c) An application for higher limits pursuant to paragraph (b) of this section shall include information demonstrating that the applicant has made a reasonable effort to minimize the radioactivity discharged in effluents to unrestricted areas, and shall include, as pertinent:

(1) Information as to flow rates, total volume of effluent, peak concentration of each radionuclide in the effluent, and concentration of each radionuclide in the effluent averaged over a period of one year at the point where the effluent leaves a stack, tube, pipe, or similar conduit;

(2) A description of the properties of the effluents, including:

(i) Chemical composition;

(ii) Physical characteristics, including suspended solids content in liquid effluents, and nature of gas or aerosol for air effluents;

29 FR 14434

(iii) The hydrogen ion concentrations (p^H) of liquid effluents; and

(iv) The size range of particulates in effluents released into air.

(3) A description of the anticipated human occupancy in the unrestricted area where the highest concentration of radioactive material from the effluent is expected, and, in the case of a river or stream, a description of water uses downstream from the point of release of the effluent.

(4) Information as to the highest concentration of each radionuclide in an unrestricted area, including anticipated concentrations averaged over a period of one year:

(i) In air at any point of human occupancy; or

(ii) In water at points of use downstream from the point of release of the effluent.

(5) The background concentration of radionuclides in the receiving river or stream prior to the release of liquid effluent.

(6) A description of the environmental monitoring equipment, including sensitivity of the system, and procedures and calculations to determine concentrations of radionuclides in the unrestricted area and possible recontrations of radionuclides.

(7) A description of the waste treatment facilities and procedures used to reduce the concentration of radionuclides in effluents prior to their release.

(d) For the purposes of this section the concentration limits in Appendix B, Table II of this part shall apply at the boundary of the restricted area. The concentration of radioactive material discharged through a stack, pipe or similar conduit may be determined with respect to the point where the material leaves the conduit. If the conduit discharges within the restricted area, the concentration at the boundary may be determined by applying appropriate factors for dilution, dispersion, or decay between the point of discharge and the boundary.

29 FR 14434

(e) In addition to limiting concentrations in effluent streams, the Commission may limit quantities of radioactive materials released in air or water during a specified period of time if it appears that the daily intake of radioactive material from air, water, or food by a suitable sample of an exposed population group, averaged over a period not exceeding one year, would otherwise exceed the daily intake resulting from continuous exposure to air or water containing one-third the concentration of radioactive materials specified in Appendix B, Table II of this part.

(f) The provisions of paragraphs (a) through (e) of this section do not apply to disposal of radioactive material into sanitary sewerage systems, which is governed by § 20.303.

(g) In addition to other requirements of this part, licensees engaged in uranium fuel cycle operations subject to the provisions of 40 CFR Part 190, "Environmental Radiation Protection Standard for Nuclear Power Operations," shall comply with that part.

46 FR 18525

§ 20.107 Medical diagnosis and therapy.

Nothing in the regulations in this part shall be interpreted as limiting the intentional exposure of patients to radiation for the purpose of medical diagnosis or medical therapy.

§ 20.108 Orders requiring furnishing of bio-assay services.

Where necessary or desirable in order to aid in determining the extent of an individual's exposure to concentrations of radioactive material, the Commission may incorporate appropriate provisions in any license, directing the licensee to make available to the individual appropriate bio-assay services and to furnish a copy of the reports of such services to the Commission.

25 FR 10914

PRECAUTIONARY PROCEDURES

§ 20.201 Surveys.

(a) As used in the regulations in this part, "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions. When appropriate, such evaluation includes a physical survey of the location of materials and equipment, and measurements of levels of radiation or concentrations of radioactive material present.

25 FR 10914

(b) Each licensee shall make or cause to be made such surveys as (1) may be necessary for the licensee to comply with the regulations in this part, and (2) are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present.

46 FR 53647

§ 20.202 Personnel monitoring.

(a) Each licensee shall supply appropriate personnel monitoring equipment to, and shall require the use of such equipment by:

(1) Each individual who enters a restricted area under such circumstances that he receives, or is likely to receive, a dose in any calendar quarter in excess of 25 percent of the applicable value specified in paragraph (a) of § 20.101.

(2) Each individual under 18 years of age who enters a restricted area under such circumstances that he receives, or is likely to receive, a dose in any calendar quarter in excess of 5 percent of the applicable value specified in paragraph (a) of § 20.101.

(3) Each individual who enters a high radiation area.

25 FR 10914

(b) As used in this part,

(1) "Personnel monitoring equipment" means devices designed to be worn or carried by an individual for the purpose of measuring the dose received (e.g., film badges, pocket chambers, pocket dosimeters, film rings, etc.);

(2) "Radiation area" means any area, accessible to personnel, in which there exists radiation, originating in whole or in part within licensed material, at such levels that a major portion of the body could receive in any one hour a dose in excess of 5 millirem, or in any 5 consecutive days a dose in excess of 100 millirems;

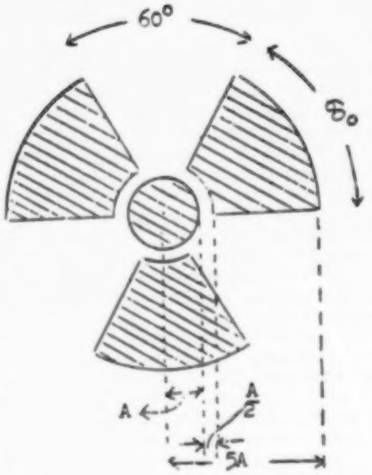
(3) "High radiation area" means any area, accessible to personnel, in which there exists radiation originating in whole or in part within licensed material at such levels that a major portion of the body could receive in any one hour a dose in excess of 100 millirem.

§ 20.203 Caution signs, labels, signals and controls.

(a) *General.* (1) Except as otherwise authorized by the Commission, symbols prescribed by this section shall use the conventional radiation caution colors (magenta or purple on yellow background). The symbol prescribed by this section is the conventional three-bladed design:

RADIATION SYMBOL

1. Cross-hatched area is to be magenta or purple.
2. Background is to be yellow.



(2) In addition to the contents of signs and labels prescribed in this section, licensees may provide on or near such signs and labels any additional information which may be appropriate in aiding individuals to minimize exposure to radiation or to radioactive material.

(b) *Radiation areas.* Each radiation area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

CAUTION [1]

RADIATION AREA

(c) *High radiation areas.* (1) Each high radiation area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

CAUTION [1]

HIGH RADIATION AREA

35 FR 5033

(2) Each entrance or access point to a high radiation area shall be:

(i) Equipped with a control device which shall cause the level of radiation to be reduced below that at which an individual might receive a dose of 100 millirems in 1 hour upon entry into the area; or

(ii) Equipped with a control device which shall energize a conspicuous visible or audible alarm signal in such a manner that the individual entering the high radiation area and the licensee or a supervisor of the activity are made aware of the entry; or

(iii) Maintained locked except during periods when access to the area is required, with positive control over each individual entry.

(3) The controls required by paragraph (c)(2) of this section shall be established in such a way that no individual will be prevented from leaving a high radiation area.

(4) In the case of a high radiation area established for a period of 30 days or less, direct surveillance to prevent unauthorized entry may be substituted for the controls required by paragraph (c)(2) of this section.

(5) Any licensee, or applicant for a license, may apply to the Commission for approval of methods not included in paragraphs (c)(2) and (4) of this section for controlling access to high radiation areas. The Commission will approve the proposed alternatives if the licensee or applicant demonstrates that the alternative methods of control will prevent unauthorized entry into a high radiation area, and that the requirement of paragraph (c)(3) of this section is met.

35 FR 5033

(6) Each area in which there may exist radiation levels in excess of 500 rems in one hour at one meter from a sealed radio-active source [3] that is used to irradiate materials shall: [4]

42 FR 64619

(i) Have each entrance or access point equipped with entry control devices which shall function automatically to prevent any individual from inadvertently entering the area when such radiation levels exist; permit deliberate entry into the area only after a control device is actuated that shall cause the radiation level within the area, from the sealed source, to be reduced below that at which it would be possible for an individual to receive a dose in excess of 100 mrem in one hour; and prevent operation of the source if the source would produce radiation levels in the area that could result in a dose to an individual in excess of 100 mrem in one hour. The entry control devices required by this paragraph (c)(6) shall be established in such a way that no individual will be prevented from leaving the area.

43 FR 2167

(ii) Be equipped with additional control devices such that upon failure of the entry control devices to function as required by paragraph (c)(6)(i) of this section the radiation level within the area, from the sealed source, shall be reduced below that at which it would be possible for an individual to receive a dose in excess of 100 mrem in one hour; and visible and audible alarm signals shall be generated to make an individual attempting to enter the area aware of the hazard and the licensee or at least one other individual, who is familiar with the activity and prepared to render or summon assistance, aware of such failure of the entry control devices.

(iii) Be equipped with control devices such that upon failure or removal of physical radiation barriers other than the source's shielded storage container the radiation level from the source shall be reduced below that at which it would be possible for an individual to receive a dose in excess of 100 mrem in one hour; and visible and audible alarm signals shall be generated to make potentially affected individuals aware of the hazard and the licensee or at least one other individual, who is familiar with the activity and prepared to render or summon assistance, aware of the failure or removal of the physical barrier. When the shield for the stored source is a liquid, means shall be provided to monitor the integrity of the shield and to signal, automatically, loss of adequate shielding. Physical radiation barriers that com-

42 FR 64619

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[1] Or "Danger".

[3] This paragraph (c)(6) does not apply to radioactive sources that are used in teletherapy, in radiography, or in completely self-shielded irradiators in which the source is both stored and operated within the same shelding radiation barrier and, in the designed configuration of the irradiator, is always physically inaccessible to any individual and cannot create high levels of radiation in an area that is accessible to any individual. This paragraph (c)(6) also does not apply to sources from which the radiation is incidental to some other use nor to nuclear reactor generated radiation other than radiation from byproduct, source, or special nuclear materials that are used in sealed sources in non-self-shielded irradiators.

[4] These requirements apply after Mar. 14, 1978. Each person licensed to conduct activities to which this paragraph (c)(6) applies and who is not in compliance with the provisions of this paragraph on Mar. 14, 1978, shall file with the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, on or before June 14, 1978, information describing in detail the actions taken or to be taken to achieve compliance with this paragraph by Dec. 14, 1978, and may continue activities in conformance with present license conditions and the provisions of the previously effective § 20.2034 until such compliance is achieved. For such persons compliance must be achieved not later than Dec. 14, 1978.

prise permenent structural components, such as walls, that have no credible probability of failure or removal in ordinary circumstances need not meet the requirements of this paragraph (c)(6)(iii).

(iv) Be equipped with devices that will automatically generate visible and audible alarm signals to alert personnel in the area before the source can be put into operation and in sufficient time for any individual in the area to operate a clearly identified control device which shall be installed in the area and which can prevent the source from being put into operation.

42 FR 64619

(v) Be controlled by use of such administrative procedure and such devices as are necessary to assure that the area is cleared of personnel prior to each use of the source preceding which use it might have been possible for an individual to have entered the area.

43 FR 2167

(vi) Be checked by a physical radiation measurement to assure that prior to the first individual's entry into the area after any use of the source, the radiation level from the source in the area is below that at which it would be possible for an individual to receive a dose in excess of 100 mrem in one hour.

(vii) Have entry control devices required in paragraph (c)(6)(i) of this section which have been tested for proper functioning prior to initial operation with such source of radiation on any day that operations are not uninterruptedly continued from the previous day or before resuming operations after any unintended interruption, and for which records are kept of the dates, times, and results of such tests of function. No operations other than those necessary to place the source in safe condition or to effect reparis on controls shall be conducted with such source unless control devices are functioning properly. The licensee shall submit an acceptable schedule for more complete periodic tests of the entry control and warning systems to be established and adhered to as a condition of the license.

(viii) Have those entry and exit portals that are used in transporting materials to and from the irradiation area, and that are not intended for use by individuals, controlled by such devices and administrative procedures as are necessary to physically protect and warn against inadvertent entry by any individual through such portals. Exit portals for processed materials shall be equipped to detect and signal the presence of loose radiation sources that are carried toward such an exit and to automatically prevent such loose sources from being carried out of the area.

42 FR 64619

(7) Licensees with, or applicants for, licenses for radiation sources that are within the purview of paragraph (c)(6) of this section, and that must be used in a variety of positions or in peculiar locations, such as open fields or forests, that make it impracticable to comply with certain requirements of paragraph (c)(6) of this section, such as those for the automatic control of radiation levels, may apply to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, for approval, prior to use of safety measures that are alternative to those specified in paragraph (c)(6) of this section, and that will provide at least an equivalent degree of personnel protection in the use of such sources. At least one of the alternative measures must include an entry-preventing interlock control based on a physical measurement of radiation that assures the absence of high radiation levels before an individual can gain access to an area where such sources are used.

43 FR 2167

(d) *Airborne radioactivity areas.* (1) As used in the regulations in this part "airborne radioactivity area" means (i) any room, enclosure, or operating area in which airborne radioactive materials composed wholly or partly of licensed material, exist in concentrations in excess of the amounts specified in Appendix B, Table I, Column 1 of this part; or (ii) any room, enclosure, or operating area in which airborne radioactive material composed wholly or partly of licensed material exists in concentrations which, averaged over the number of hours in any week during which individuals are in the area, exceed 25 percent of the amounts specified in Appendix B Table I, Column 1 of this part.

(2) Each airborne radioactivity area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

CAUTION [1]

AIRBORNE RADIOACTIVITY AREA

(e) *Additional requirements.* (1) Each area or room in which licensed material is used or stored and which contains any radioactive material (other than natural uranium or thorium) in an amount exceeding 10 times the quantity of such material specified in Appendix C of this part shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

25 FR 10914

CAUTION [1]

RADIOACTIVE MATERIAL(S)

(2) Each area or room in which natural uranium or thorium is used or stored in any amount exceeding one hundred times the quantity specified in Appendix C of this part shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

25 FR 10914

CAUTION [1]

RADIOACTIVE MATERIAL(S)

(f) *Containers.* (1) Except as provided in paragraph (f)(3) of this section, each container of licensed material shall bear a durable, clearly visible label identifying the radioactive contents.

(2) A label required pursuant to paragraph (f)(1) of this section shall bear the radiation caution symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL". It shall also provide sufficient information [2] to permit individuals handling or using the containers, or working in the vicinity thereof, to take precautions to avoid or minimize exposures.

(3) Notwithstanding the provisions of paragraph (f)(1) of this section labeling is not required:

(i) For containers that do not contain licensed materials in quantities greater than the applicable quantities listed in Appendix C of this part.

(ii) For containers containing only natural uranium or thorium in quantities no greater than 10 times the applicable quantities listed in Appendix C of this part.

(iii) For containers that do not contain licensed materials in concentrations greater than the applicable concentrations listed in Appendix B, Table I, Column 2, of this part.

(iv) For containers when they are attended by an individual who takes the precautions necessary to prevent the exposure of any individual to radiation or radioactive materials in excess of the limits established by the regulations in this part.

31 FR 10514

(v) For containers when they are in transport and packaged and labeled in accordance with regulations of the Department of Transportation.

34 FR 19546

(vi) For containers which are accessible [2] only to individuals authorized to handle or use them, or to work in the vicinity thereof, provided that the contents are identified to such individuals by a readily available written record.

(vii) For manufacturing or process equipment, such as nuclear reactors, reactor components, piping, and tanks.

31 FR 10514

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[1] Or "Danger".

[2] As appropriate, the information will include radiation levels, kinds of material, estimate of activity, date for which activity is estimated, mass enrichment, etc.

(4) Each licensee shall, prior to disposal of an empty uncontaminated container to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials. 43 FR 22171

§ 20.204 Same: exceptions.

Notwithstanding the provisions of § 20.203,

(a) A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level twelve inches from the surface of the source container or housing does not exceed five millirem per hour. 25 FR 10914

(b) Rooms or other areas in hospitals are not required to be posted with caution signs, and control of entrance or access thereto pursuant to § 20.203(c) is not required, because of the presence of patients containing byproduct material provided that there are personnel in attendance who will take the precautions necessary to prevent the exposure of any individual to radiation or radioactive material in excess of the limits established in the regulations in this part. 35 FR 5033

(c) Caution signs are not required to be posted at areas or rooms containing radioactive materials for periods of less than eight hours provided that (1) the materials are constantly attended during such periods by an individual who shall take the precautions necessary to prevent the exposure of any individual to radiation or radioactive materials in excess of the limits established in the regulations in this part and; (2) such area or room is subject to the licensee's control. 25 FR 10914

(d) A room or other area is not required to be posted with a caution sign, and control is not required for each entrance or access point to a room or other area which is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with regulations of the Department of Transportation. 35 FR 5033

§ 20.205 Procedures for picking up, receiving, and opening packages.

(a)(1) Each licensee who expects to receive a package containing quantities of radioactive material in excess of the Type A quantities specified in paragraph (b) of this section shall:

(i) If the package is to be delivered to the licensee's facility by the carrier, make arrangements to receive the package when it is offered for delivery by the carrier; or

(ii) If the package is to be picked up by the licensee at the carrier's terminal, make arrangements to receive notification from the carrier of the arrival of the package, at the time of arrival.

(2) Each licensee who picks up a package of radioactive material from a carrier's terminal shall pick up the package expeditiously upon receipt of notification from the carrier of its arrival.

(b)(1) Each licensee, upon receipt of a package of radioactive material, shall monitor the external surfaces of the package for radioactive contamination caused by leakage of the radioactive contents, except:

(i) Packages containing no more than the exempt quantity specified in the table in this paragraph;

(ii) Packages containing no more than 10 millicuries of radioactive material consisting solely of tritium, carbon-14, sulfur-35, or iodine-125;

(iii) Packages containing only radioactive material as gases or in special form;

(iv) Packages containing only radioactive material in other than liquid form (including Mo-99/Tc-99m generators) and not exceeding the Type A quantity limit specified in the table in this paragraph; and

(v) Packages containing only radionuclides with half-lives of less than 30 days and a total quantity of no more than 100 millicuries.

The monitoring shall be performed as soon as practicable after receipt, but no later than three hours after the package is received at the licensee's facility if received during the licensee's normal working hours, or eighteen hours if received after normal working hours. 39 FR 17972

(2) If removable radioactive contamination in excess of 0.01 microcuries (22,000 disintegrations per minute) per 100 square centimeters of package surface is found on the external surfaces of the package, the licensee shall immediately notify the final delivering carrier and, by telephone and telegraph, mailgram or facsimile, the appropriate Nuclear Regulatory Commission Inspection and Enforcement Regional Office shown in Appendix D of this part. 41 FR 16445

TABLE OF EXEMPT AND TYPE A QUANTITIES

Transport group [1]	Exempt quantity limit (in millicuries)	Type A quantity limit (in curies)
I	.01	0.001
II	0.1	0.050
III	1	3
IV	1	20
V	1	20
VI	1	1000
VII	25,000	1000
Special Form	1	20

[1] The definitions of "transport group" and "special form" are specified in § 71.4 of this chapter.

[Footnote 1 removed 49 FR 19623]

(c)(1) Each licensee, upon receipt of a package containing quantities of radioactive material in excess of the Type A quantities specified in paragraph (b) of this section, other than those transported by exclusive use vehicle, shall monitor the radiation levels external to the package. The package shall be monitored as soon as practicable after receipt, but no later than three hours after the package is received at the licensee's facility if received during the licensee's normal working hours, or 18 hours if received after normal working hours.

(2) If radiation levels are found on the external surface of the package in excess of 200 millirem per hour, or at three feet from the external surface of the package in excess of 10 millirem per hour, 39 FR 17972

the licensee shall immediately notify by telephone and telegraph mailgram, or facsimile, the director of the appropriate NRC Regional Office listed in Appendix D, and the final delivering carrier. [41 FR 16445]

(d) Each licensee shall establish and maintain procedures for safely opening packages in which licensed material is received, and shall assure that such procedures are followed and that due consideration is given to special instructions for the type of package being opened. 39 FR 17972

§ 20.206 Instruction of personnel.

Instructions required for individuals working in or frequenting any portion of a restricted area are specified in § 19.12 of this chapter. 38 FR 22220

§ 20.207 Storage and control of licensed materials in unrestricted areas.

(a) Licensed materials stored in an unrestricted area shall be secured from unauthorized removal from the place of storage.

(b) Licensed materials in an unrestricted area and not in storage shall be 40 FR 26679

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[3] For example, containers in locations such as water-filled canals, storage vaults, or hot cells.

tended under the constant surveillance and immediate control of the licensee.

WASTE DISPOSAL

47 FR 57446

§ 20.301 General requirement.

No licensee shall dispose of licensed material except:

(a) By transfer to an authorized recipient as provided in the regulations in Parts 30, 40, 60, 61, 70 or 72 of this chapter, whichever may be applicable; or

(b) As authorized under § 20.302 or Part 61 of this chapter; or

46 FR 16230

(c) As provided in § 20.303, applicable to the disposal of licensed material by release into sanitary sewerage systems, or in § 20.306 for disposal of specific wastes, or in § 20.106 (Radioactivity in effluents to unrestricted areas).

36 FR 23138

§ 20.302 Method for obtaining approval of proposed disposal procedures.

(a) Any licensee or applicant for a license may apply to the Commission for approval of proposed procedures to dispose of licensed material in a manner not otherwise authorized in the regulations in this chapter. Each application should include a description of the licensed material and any other radioactive material involved, including the quantities and kinds of such material and the levels of radioactivity involved, and the proposed manner and conditions of disposal. The application should also include an analysis and evaluation of pertinent information as to the nature of the environment, including topographical, geological, meteorological, and hydrological characteristics; usage of ground and surface waters in the general area; the nature and location of other potentially affected facilities; and procedures to be observed to minimize the risk of unexpected or hazardous exposures.

47 FR 57446

(b) The Commission will not approve any application for a license for disposal of licensed material at sea unless the applicant shows that sea disposal offers less harm to man or the environment than other practical alternative methods of disposal.

25 FR 10914

§ 20.303 Disposal by release into sanitary sewerage systems.

No licensee shall discharge licensed material into a sanitary sewerage system unless:

(a) It is readily soluble or dispersible in water; and

(b) The quantity of any licensed or other radioactive material released into the system by the licensee in any one day does not exceed the larger of paragraphs (b)(1) or (2) of this section.

(1) The quantity which, if diluted by the average daily quantity of sewage released into the sewer by the licensee, will result in an average concentration equal to the limits specified in Appendix B, Table I, Column 2 of this part; or

(2) Ten times the quantity of such material specified in Appendix C of this part; and

(c) The quantity of any licensed or other radioactive material released in any one month, if diluted by the average monthly quantity of water released by the licensee, will not result in an average concentration exceeding the limits specified in Appendix B, Table I, Column 2 of this part; and

46 FR 16230

(d) The gross quantity of licensed and other radioactive material, excluding hydrogen-3 and carbon-14, released into the sewerage system by the licensee does not exceed one curie per year. The quantities of hydrogen-3 and carbon-14 released into the sanitary sewerage system may not exceed 5 curies per year for hydrogen-3 and 1 curie per year for carbon-14. Excreta from individuals undergoing medical diagnosis or therapy with radioactive material shall be exempt from any limitations contained in this section.

§ 20.305 Treatment or disposal by incineration.

No licensee shall treat or dispose of licensed material by incineration except for materials listed under § 20.306 or as specifically approved by the Commission pursuant to §§ 20.106(b) and 20.302.

§ 20.306 Disposal of specific wastes.

Any licensee may dispose of the following licensed material without regard to its radioactivity:

(a) 0.05 microcuries or less of hydrogen-3 or carbon-14, per gram of medium, used for liquid scintillation counting; and

(b) 0.05 microcuries or less of hydrogen-3 or carbon-14, per gram of animal tissue averaged over the weight of the entire animal; provided however, tissue may not be disposed of under this section in a manner that would permit its use either as food for humans or as animal feed.

(c) Nothing in this section, however, relieves the licensee of maintaining records showing the receipt, transfer and disposal of such byproduct material as specified in § 30.51 of this chapter; and

(d) Nothing in this section relieves the licensee from complying with other applicable Federal, State and local regulations governing any other toxic or hazardous property of these materials.

47 FR 57446

§ 20.311 Transfer for disposal and manifests.

(a) Purpose. The requirements of this section are designed to control transfers of radioactive waste intended for disposal at a land disposal facility and establish a manifest tracking system and supplement existing requirements concerning transfers and recordkeeping for such wastes. The reporting and recordkeeping requirements contained in this section have been approved by the Office of Management and Budget; OMB approval No. 3150–0014.

(b) Each shipment of radioactive waste to a licensed land disposal facility must be accompanied by a shipment manifest that contains the name, address, and telephone number of the person generating the waste. The manifest shall also include the name, address, and telephone number or the name and EPA hazardous waste identification number of the person transporting the waste to the land disposal facility. The manifest must also indicate as completely as practicable: a physical description of the waste; the volume; radionuclide identity and quantity; the total radioactivity; and the principal chemical form. The solidification agent must be specified. Waste containing more than 0.1% chelating agents by weight must be identified and the weight percentage of the chelating agent estimated. Wastes classified as Class A, Class B, or Class C in § 61.55 of this chapter must be clearly identified as such in the manifest. The total quantity of the radionuclides H–3, C–14, Tc–99 and I–129 must be shown. The manifest required by this paragraph may be shipping papers used to meet Department of Transportation or

Environmental Protection Agency regulations or requirements of the receiver, provided all the required information is included. Copies of manifests required by this section may be legible carbon copies or legible photocopies.

(c) Each manifest must include a certification by the waste generator that the transported materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the Department of Transportation and the Commission. An authorized representative of the waste generator shall sign and date the manifest.

(d) Any generating licensee who transfers radioactive waste to a land disposal facility or a licensed waste collector shall comply with the requirements in paragraphs (d)(1) through (8) of this section. Any generating licensee who transfers waste to a licensed waste processor who treats or repackages waste shall comply with the requirements of paragraphs (d)(4) through (8) of this section. A licensee shall:

47 FR 57446

(1) Prepare all wastes so that the waste is classified according to § 61.55 and meets the waste characteristics requirements in § 61.56 of this chapter;

(2) Label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with § 61.55 of this chapter;

(3) Conduct a quality control program to assure compliance with §§ 61.55 and 61.56 of this chapter; the program must include management evaluation of audits;

(4) Prepare shipping manifests to meet the requirements of §§ 20.311 (b) and (c) of this part;

(5) Forward a copy of the manifest to the intended recipient, at the time of shipment; or, deliver to a collector at the time the waste is collected, obtaining acknowledgement of receipt in the form of a signed copy of the manifest or equivalent documentation from the collector;

(6) Include one copy of the manifest with the shipment;

(7) Retain a copy of the manifest and documentation of acknowledgement of receipt as the record of transfer of licensed material as required by Parts 30, 40, and 70 of this chapter; and,

(8) For any shipments or any part of a shipment for which acknowledgement of receipt has not been received within the times set forth in this section, conduct an investigation in accordance with paragraph (h) of this section.

(e) Any waste collector licensee who handles only prepackaged waste shall:

(1) Acknowledge receipt of the waste from the generator within one week of receipt by returning a signed copy of the manifest or equivalent documentation;

(2) Prepare a new manifest to reflect consolidated shipments; the new manifest shall serve as a listing or index for the detailed generator manifests. Copies of the generator manifests shall be a part of the new manifest. The waste collector may prepare a new manifest without attaching the generator manifests, provided the new manifest contains for each package the information specified in paragraph (b) of this section. The collector licensee shall certify that nothing has been done to the waste which would invalidate the generator's certification;

(3) Forward a copy of the new manifest to the land disposal facility operator at the time of shipment;

(4) Include the new manifest with the shipment to the disposal site;

(5) Retain a copy of the manifest and documentation of acknowledgement of receipt as the record of transfer of licensed material as required by Parts 30, 40, and 70 of this chapter, and retain information from generator manifests until disposition is authorized by the Commission; and,

47 FR 57446

(6) For any shipments or any part of a shipment for which acknowledgement of receipt is not received within the times set forth in this section, conduct an investigation in accordance with paragraph (h) of this section.

(f) Any licensed waste processor who treats or repackages wastes shall:

(1) Acknowledge receipt of the waste from the generator within one week of receipt by returning a signed copy of the manifest or equivalent documentation;

(2) Prepare a new manifest that meets the requirements of paragraphs (b) and (c) of this section. Preparation of the new manifest reflects that the processor is responsible for the waste;

(3) Prepare all wastes so that the waste is classified according to § 61.55 and meets the waste characteristics requirements in § 61.56 of this chapter;

(4) Label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with §§ 61.55 and 61.57 of this chapter;

(5) Conduct a quality control program to assure compliance with §§ 61.55 and 61.56 of this chapter. The program shall include management evaluation of audits;

(6) Forward a copy of the new manifest to the disposal site operator or waste collector at the time of shipment, or deliver to a collector at the time the waste is collected, obtaining acknowledgement of receipt in the form of a signed copy of the manifest or equivalent documentation by the collector;

(7) Include the new manifest with the shipment;

(8) Retain copies of original manifests and new manifests and documentation of acknowledgement of receipt as the record of transfer of licensed material required by Parts 30, 40, and 70 of this chapter; and

(9) For any shipment or part of a shipment for which acknowledgement is not received within the times set forth in this section, conduct an investigation in accordance with paragraph (h) of this section.

(g) The land disposal facility operator shall:

(1) Acknowledge receipt of the waste within one week of receipt by returning a signed copy of the manifest or equivalent documentation to the shipper. The shipper to be notified is the licensee who last possessed the waste and transferred the waste to the operator. The returned copy of the manifest or equivalent documentation shall indicate any discrepancies between materials listed on the manifest and materials received;

47 FR 57446

(2) Maintain copies of all completed manifests or equivalent documentation until the Commission authorizes their disposition; and

(3) Notify the shipper (i.e., the generator, the collector, or processor) and the Director of the nearest Commission Regional Office listed in Appendix D of this part when any shipment or part of a shipment has not arrived within 60 days after the advance manifest was received.

(h) Any shipment or part of a shipment for which acknowledgement is not received within the times set forth in this section, must:

(1) Be investigated by the shipper if the shipper has not received notification of receipt within 20 days after transfer; and

(2) Be traced and reported. The investigation shall include tracing the shipment and filing a report with the nearest Commission Regional Office listed in Appendix D of this part. Each licensee who conducts a trace investigation shall file a written report with the nearest Commission's Regional office within 2 weeks of completion of the investigation.

25 FR 10914

§ 20.401 Records of surveys, radiation monitoring, and disposal.

(a) Each licensee shall maintain records showing the radiation exposures of all individuals for whom personnel monitoring is required under § 20.202 of the regulations in this part. Such records shall be kept on Form NRC-5, in accordance with the instructions contained in that form or on clear and legible records containing all the information required by Form NRC-5. The doses entered on the forms or records shall be for periods of time not exceeding one calendar quarter.

47 FR 57446

(b) Each licensee shall maintain records in the same units used in this part, showing the results of surveys required by § 20.201(b), monitoring required by §§ 20.205(b) and 20.205(c), and disposals made under §§ 20.302, 20.303, removed § 20.304,[1] and Part 61 of this chapter.

41 FR 18300

(c)(1) Records of individual exposure to radiation and to radioactive material which must be maintained pursuant to the provisions of paragraph (a) of this section and records of bioassays, including results of whole body counting examinations, made pursuant to § 20.108, shall be preserved until the Commission authorizes disposition.

(2) Records of the results of surveys and monitoring which must be maintained pursuant to paragraph (b) of this section shall be preserved for two years after completion of the survey except that the following records shall be maintained until the Commission authorizes their disposition: (i) Records of the results of surveys to determine compliance with § 20.103(a); (ii) in the absence of personnel monitoring data, records of the results of surveys to determine external radiation dose; and (iii) records of the results of surveys used to evaluate the release of radioactive effluents to the environment.

(next page is 20-11)

47 FR 57446

(3) Records of disposal of licensed materials made pursuant to §§ 20.302, 20.303, removed § 20.304,[1] and Part 61 of this chapter are to be maintained until the Commission authorizes their disposition.

41 FR 18300

(4) Records which must be maintained pursuant to this part may be the original or a reproduced copy or microform if such reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified by Commission regulations.

(5) If there is a conflict between the Commission's regulations in this part, license condition, or technical specification, or other written Commission approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the regulations in this part for such records shall apply unless the Commission pursuant to § 20.501, has granted a specific exemption from the record retention requirements specified in the regulations in this part.

48 FR 33850

§ 20.402 Reports of theft or loss of licensed material.

(a)(1) Each licensee shall report to the Commission, by telephone, immediately after it determines that a loss or theft of licensed material has occurred in such quantities and under such circumstances that it appears to the licensee that a substantial hazard may result to persons in unrestricted areas.

(2) Reports must be made as follows:

(i) Licensees having an installed Emergency Notification System shall make the reports to the NRC Operations Center in accordance with § 50.72 of this chapter.

(ii) All other licensees shall make reports to the Administrator of the appropriate NRC Regional Office listed in Appendix D of this part.

(b) Each licensee who makes a report under paragraph (a) of this section shall, within 30 days after learning of the loss or theft, make a report in writing to the U.S. Nuclear Regulatory Commission, Document Control Desk, Washington, D.C. 20555, with a copy to the appropriate NRC Regional Office listed in Appendix D of this part. The report shall include the following information:

34 FR 7500

(1) A description of the licensed material involved, including kind, quantity, chemical, and physical form;

(2) A description of the circumstances under which the loss or theft occurred;

(3) A statement of disposition or probable disposition of the licensed material involved;

(4) Radiation exposures to individuals, circumstances under which the exposures occurred, and the extent of possible hazard to persons in unrestricted areas;

(5) Actions which have been taken, or will be taken, to recover the material; and

(6) Procedures or measures which have been or will be adopted to prevent a recurrence of the loss or theft of licensed material.

(c) Subsequent to filing the written report the licensee shall also report any substantive additional information on the loss or theft which becomes available to the licensee, within 30 days after he learns of such information.

(d) Any report filed with the Commission pursuant to this section shall be so prepared that names of individuals who may have received exposure to radiation are stated in a separate part of the report.

48 FR 33850

(e) For holders of an operating license for a nuclear power plant, the events included in paragraph (b) of this section must be reported in accordance with the procedures described in § 50.73 (b), (c), (d), (e), and (g) of this chapter and must include the information required in paragraph (b) of this section. Events reported in accordance with § 50.73 of this chapter need not be reported by a duplicate report under paragraph (b) of this section.

§ 20.403 Notifications of incidents.

(a) *Immediate notification.* Each licensee shall immediately report any events involving byproduct, source, or special nuclear material possessed by the licensee that may have caused or threatens to cause:

37 FR 5905

(1) Exposure of the whole body of any individual to 25 rems or more of radiation; exposure of the skin of the whole body of any individual of 150 rems or more or radiation; or exposure of the feet, ankles, hands or forearms of any individual to 375 rems or more of radiation; or

(2) The release of radioactive material in concentrations which, if averaged over a period of 24 hours, would exceed 5,000 times the limits specified for such materials in Appendix B, Table II of this part; or

(3) A loss of one working week or more of the operation of any facilities affected; or

42 FR 43965

(4) Damage to property in excess of $200,000.

48 FR 33850

(b) *Twenty-four hour notification.* Each licensee shall within 24 hours of discovery of the event, report any event involving licensed material possessed by the licensee that may have caused or threatens to cause:

37 FR 5905

(1) Exposure of the whole body of any individual to 5 rems or more of radiation; exposure of the skin of the whole body of any individual to 30 rems or more of radiation; or exposure of the feet, ankles, hands, or forearms to 75 rems or more of radiation; or

(2) The release of radioactive material in concentrations which, if averaged over a period of 24 hours, would exceed 500 times the limits specified for such materials in Appendix B, Table II of this part; or

(3) A loss of one day or more of the operation of any facilities affected; or

42 FR 43965

(4) Damage to property in excess of $2,000.

28 FR 6822

(c) Any report filed with the Commission pursuant to this section shall be prepared so that names of individuals who have received exposure to radiation will be stated in a separate part of the report.

48 FR 33850

(d) Reports made by licensees in response to the requirements of this section must be made as follows:

(1) Licensees that have an installed Emergency Notification System shall make the reports required by paragraphs (a) and (b) of this section to the NRC Operations Center in accordance with § 50.72 of this chapter.

(2) All other licensees shall make the reports required by paragraphs (a) and (b) of this section by telephone and by telegram, mailgram, or facsimile to the Administrator of the appropriate NRC Regional Office listed in Appendix D of this part.

§ 20.404 [Reserved]

48 FR 33850

§ 20.405 Reports of overexposures and excessive levels and concentrations.

(a)(1) In addition to any notification required by § 20.403 of this part, each licensee shall make a report in writing concerning any one of the following types of incidents within 30 days of its occurrence:

(i) Each exposure of an individual to radiation in excess of the applicable limits in §§ 20.101 or 20.104(a) of this part, or the license;

(ii) Each exposure of an individual to radioactive material in excess of the applicable limits in §§ 20.103(a)(1), 20.103(a)(2), or 20.104(b) of this part, or in the license;

48 FR 33850

(iii) Levels of radiation or concentrations of radioactive material in a restricted area in excess of any other applicable limit in the license;

(iv) Any incident for which notification is required by § 20.403 of this part; or

(v) Levels of radiation or concentrations of radioactive material (whether or not involving excessive exposure of any individual) in an unrestricted area in excess of ten times any applicable limit set forth in this part or in the license.

(2) Each report required under paragraph (a)(1) of this section must describe the extent of exposure of individuals to radiation or to radioactive material, including:

(i) Estimates of each individual's exposure as required by paragraph (b) of this section;

(ii) Levels of radiation and concentrations of radioactive material involved;

(iii) The cause of the exposure, levels or concentrations; and

(iv) Corrective steps taken or planned to prevent a recurrence.

46 FR 18525

(b) Any report filed with the Commission pursuant to paragraph (a) of this section shall include for each individual exposed the name, social security number, and date of birth, and an estimate of the individual's exposure. The report shall be prepared so that this information is stated in a separate part of the report.

48 FR 33850

(c)(1) In addition to any notification required by § 20.403 of this part, each licensee shall make a report in writing of levels of radiation or releases of radioactive material in excess of limits specified by 40 CFR Part 190, "Environmental Radiation Protection Standards for Nuclear Power Operations," or in excess of license conditions related to compliance with 40 CFR Part 190.

(2) Each report submitted under paragraph (c)(1) of this section must describe:

(i) The extent of exposure of individuals to radiation or to radioactive material;

(ii) Levels of radiation and concentrations of radioactive material involved;

(iii) The cause of the exposure, levels, or concentrations; and

(iv) Corrective steps taken or planned to assure against a recurrence, including the schedule for achieving conformance with 40 CFR Part 190 and with associated license conditions.

(d) For holders of an operating license for a nuclear power plant, the incidents included in paragraphs (a) or (c) of this section must be reported in accordance with the procedures described in paragraphs 50.73 (b), (c), (d), (e), and (g) of this chapter and must also include the information required by paragraphs (a) and (c) of this section. Incidents reported in accordance with § 50.73 of this chapter need not be reported by a duplicate report under paragraphs (a) or (c) of this section.

(e) All other licensees who make reports under paragraphs (a) or (c) of this section shall, within 30 days after learning of the overexposure or excessive level or concentration, make a report in writing to the U.S. Nuclear Regulatory Commission, Document Control Desk, Washington, D.C. 20555, with a copy to the appropriate NRC Regional Office listed in Appendix D of this part.

43FR44827

§ 20.406 [Reserved]

49 FR 24513

§ 20.407 Personnel monitoring reports.

Each person described in § 20.408 of this part shall, within the first quarter of each calendar year, submit to the Director, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, the reports specified in paragraphs (a) and (b) of this section, covering the preceding calendar year.[1]

43 FR 44827

(a) A report of either (1) the total number of individuals for whom personnel monitoring was required under § 20.202(a) or § 34.33(a) of this chapter during the calendar year; or (2) the total number of individuals for whom personnel monitoring was provided during the calendar year: *Provided, however,* That such total includes at least the number of individuals required to be reported under paragraph (a)(1) of this section. The report shall indicate whether it is submitted in accordance with paragraph (a)(1) or (a)(2) of this section. If personnel monitoring was not required to be provided to any individual by the licensee under §§ 20.202(a) or 34.33(a) of this chapter during the calendar year, the licensee shall submit a negative report indicating that such personnel monitoring was not required.

(b) A statistical summary report of the personnel monitoring information recorded by the licensee for individuals for whom personnel monitoring was either required or provided, as described in paragraph (a) of this section, indicating the number of individuals whose total whole body exposure recorded during the previous calendar year was in each of the following estimated exposure ranges:

Estimated whole body exposure range (rems)[1]	Number of individuals in each range
No measurable exposure	
Measurable exposure less than 0.1	
0.1 to 0.25	
0.25 to 0.5	
0.5 to 0.75	
0.75 to 1	
1 to 2	
2 to 3	
3 to 4	
4 to 5	
5 to 6	
6 to 7	
7 to 8	
8 to 9	
9 to 10	
10 to 11	
11 to 12	
12+	

[1] Individual values exactly equal to the values separating exposure ranges shall be reported in the higher range.

The low exposure range data are required in order to obtain better information about the exposures actually recorded. This section does not require improved measurements.

§ 20.408 Reports of personnel monitoring on termination of employment or work.

(a) This section applies to each person licensed by the Commission to:

(1) Operate a nuclear reactor designed to produce electrical or heat energy pursuant to § 50.21(b) or § 50.22 of this chapter or a testing facility as defined in § 50.2(r) of this chapter;

(2) Possess or use byproduct material for purposes of radiography pursuant to Parts 30 and 34 of this chapter;

46 FR 13971

(3) Possess or use at any one time, for purposes of fuel processing, fabricating, or reprocessing, special nuclear material in a quantity exceeding 5,000 grams of contained uranium-235, uranium-233, or plutonium or any combination thereof pursuant to Part 70 of this chapter;

(4) Possess high-level radioactive waste at a geologic repository operations area pursuant to Part 60 of this chapter; or

46 FR 58281

(5) Possess spent fuel in an independent spent fuel storage installation (ISFSI) pursuant to Part 72 of this chapter; or

(6) Possess or use at any one time, for processing or manufacturing for distribution pursuant to Parts 30, 32, or 33 of this Chapter, byproduct material in quantities exceeding any one of the following quantities:

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[1] A licensee whose license expires or terminates prior to, or on the last day of the calendar year, shall submit reports at the expiration or termination of the license, covering that part of the year during which the license was in effect.

43 FR 44827

Radionuclide [1]	Quantity in curies
Cesium-137	1
Cobalt-60	1
Gold-198	100
Iodine-131	1
Indium-192	10
Krypton-85	1,000
Promethium-147	10
Technetium-99m	1,000

[1] The Commission may require, as a license condition, or by rule, regulation or order pursuant to § 20.502, reports from licensees who are licensed to use radionuclides not on this list, in quantities sufficient to cause comparable radiation levels.

47 FR 57446

(7) Receive radioactive waste from other persons for disposal under Part 61 of this chapter.

49 FR 24513

(b) When an individual terminates employment with a licensee described in paragraph (a) of this section, or an individual assigned to work in such a licensee's facility, but not employed by the licensee, completes the work assignment in the licensee's facility, the licensee shall furnish to the Director, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, a report of the individual's exposures to radiation and radioactive material, incurred during the period of employment or work assignment in the licensee's facility, containing information recorded by the licensee pursuant to §§ 20.401(a) and 20.108. Such report shall be furnished within 30 days after the exposure of the individual has been determined by the licensee or 90 days after the date of termination of employment or work assignment, whichever is earlier.

38 FR 22220

§ 20.409 Notifications and reports to individuals.

(a) Requirements for notifications and reports to individuals of exposure to radiation or radioactive material are specified in § 19.13 of this chapter.

(b) When a licensee is required pursuant to §§ 20.405 or 20.408 to report to the Commission any exposure of an individual to radiation or radioactive material, the licensee shall also notify the individual. Such notice shall be transmitted at a time not later than the transmittal to the Commission, and shall comply with the provisions of § 19.13(a) of this chapter.

EXCEPTIONS AND ADDITIONAL REQUIREMENTS

25 FR 10914

§ 20.501 Applications for exemptions.

The Commission may, upon application by any licensee or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not result in undue hazard to life or property.

§ 20.502 Additional requirements.

The Commission may, by rule, regulation, or order, impose upon any licensee such requirements, in addition to those established in the regulations in this part, as it deems appropriate or necessary to protect health or to minimize danger to life or property.

ENFORCEMENT

40 FR 8774

§ 20.601 Violations.

An injunction or other court order may be obtained prohibiting any violation of any provision of the Atomic Energy Act of 1954, as amended, or Title II of the Energy Reorganization Act of 1974, or any regulation or order issued thereunder. A court order may be obtained for the payment of a civil penalty imposed pursuant to section 234 of the Act for violation of section 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Act, or section 206 of the Energy Reorganization Act of 1974, or any rule, regulation, or order issued thereunder, or any term, condition, or limitation of any license issued thereunder, or for any violation for which a license may be revoked under section 186 of the Act. Any person who willfully violates any provision of the Act or any regulation or order issued thereunder may be guilty of a crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law.

[Note removed 49 FR 19623]

APPENDIX A.—PROTECTION FACTORS FOR RESPIRATORS [a]

Description [b]	Modes [c]	Protection factors [d]		Tested and certified equipment—National Institute for Occupational Safety and Health/Mine Safety and Health Administration tests for permeability
		Particulates only	Particulates, gases and vapors [e]	
I. Air-purifying respirators [f]				
Facepiece, half-mask [g]	NP	10		30 CFR Part 11, Subpart K.
Facepiece, full	NP	50		
Facepiece, half-mask, full, or hood	PP	1,000		
II. Atmosphere-supplying respirators				
1. Air-line respirator:				
Facepiece, half-mask	CF		1,000	
Facepiece, half-mask	D		5	
Facepiece, full	CF		2,000	
Facepiece, full	D		5	30 CFR Part 11, Subpart J.
Facepiece, full	PD		2,000	
Hood	CF		([h])	
Suit	CF		([i])	([j])
2. Self-contained breathing apparatus (SCBA):				
Facepiece, full	D		50	
Facepiece, full	PD		[k] 10,000	30 CFR Part 11, Subpart H.
Facepiece, full	RD		50	
Facepiece, full	RP		[l] 5,000	
III. Combination respirator: Any combination of air-purifying and atmosphere-supplying respirators.			[m]	30 CFR Part 11, § 11.63(b).

47 FR 19511

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[a] For use in the selection of respiratory protective devices to be used only where the contaminants have been identified and the concentrations (or possible concentrations) are known.

[b] Only for shaven faces and where nothing interferes with the seal of tightfitting facepieces against the skin. (Hoods and suits are excepted.)

[c] The mode symbols are defined as follows: CF = continuous flow; D = demand; NP = negative pressure (i.e., negative phase during inhalation); PD = pressure demand (i.e., always positive pressure); PP = positive pressure; RD = demand, recirculating (closed circuit); RP = positive pressure, recirculating (closed circuit).

[d-i] The protection factor is a measure of the degree of protection afforded by a respirator, defined as the ratio of the concentration of airborne radioactive material outside the respiratory protective equipment to that inside the equipment (usually inside the facepiece) under conditions of use. It is applied to the ambient airborne concentration to estimate the concentrations inhaled by the wearer according to the following formula:

$$\text{Concentration inhaled} = \frac{\text{Ambient airborne concentration}}{\text{Protection factor}}$$

[d-i] The protection factors apply:

(a) Only for trained individuals wearing properly fitted respirators used and maintained under supervision in a well-planned respiratory protective program.

(b) For air-purifying respirators only when high efficiency particulate filters (above 99.97% removal efficiency by thermally generated 0.3 μm dioctyl phthalate (DOP) test) are used in atmospheres not deficient in oxygen and not containing radioactive gas or vapor respiratory hazards.

(c) No allowance is to be made for the use of sorbents against radioactive gases or vapors.

(d) For atmosphere-supplying respirators only when supplied with adequate respirable air. Respirable air shall be provided of the quality and quantity required in accordance with NIOSH/MSHA certification (described in 30 CFR Part 11). Oxygen and air shall not be used in the same apparatus.

[e] Excluding radioactive contaminants that present an absorption or submersion hazard. For tritium oxide, approximately one half of the intake occurs by absorption through the skin so that an overall protection factor of less than 2 is appropriate when atmosphere-supplying respirators are used to protect against tritium oxide. If the protection factor for a device is 5, the effective protection factor for tritium is about 1.4; for devices with protection factors of 10 the effective factor for tritium oxide is about 1.7; and for devices with protection factors of 100 or more the effective factor for tritium oxide is about 1.9. Air-purifying respirators are not suitable for protection against tritium oxide. See also footnote i concerning supplied-air suits.

[f] Canisters and cartridges shall not be used beyond service-life limitations.

[g] Under-chin type only. This type of respirator is not satisfactory for use where it might be possible (e.g., if an accident or emergency were to occur) for the ambient airborne concentration to reach instantaneous values greater than 10 times the pertinent values in Table 1, Column 1 of Appendix B of this part. This type of respirator is not suitable for protection against plutonium or other high-toxicity materials. The mask shall be tested for fit with irritant smoke, prior to use, each time it is donned.

[h] Equipment shall be operated in a manner that ensures that proper air flow-rates are maintained. A protection factor of no more than 1000 may be used for tested-and-certified supplied-air hoods when a minimum air flow of 6 cubic feet per minute is maintained and calibrated airline pressure gauges or flow measuring devices are used. A protection factor of up to 2000 may be used for tested and certified hoods only when the air flow is maintained at the manufacturer's recommended maximum rate for the equipment, the rate is greater than 6 cubic feet per minute, and calibrated airline pressure gauges or flow measuring devices are used.

The design of the supplied-air hood or helmet (with a minimum flow of 6 cfm of air) may determine its overall efficiency and the protection it provides. For example, some hoods aspirate contaminated air into the breathing zone when the wearer works with hands-over-head. This aspiration may be overcome if a short cape-like extension to the hood is worn under a coat or overalls. Other limitations specified by the approval agency shall be considered before using a hood in certain types of atmospheres, such as the design and its permeability to the contaminant under conditions of use.

[i] Appropriate protection factors shall be determined (see 20.103(e)), taking into account the design of the suit and its permeability to the contaminant under conditions of use. There shall be a standby rescue person equipped with self-contained breathing apparatus and communications equipment whenever supplied-air suits are used.

[j] No approval schedules are currently available for this equipment. Equipment shall be evaluated by testing or on the basis of reliable test information.

[k] This type of respirator may provide greater protection and be used as an emergency device in unknown concentrations for protection against inhalation hazards. External radiation hazards and other limitations to permitted exposure such as skin absorption shall be taken into account in these circumstances.

[l] Quantitative fit testing shall be performed on each individual and no more than 0.02% leakage is allowed with this type of apparatus. Perceptible outward leakage of gas from this or any positive pressure self-contained breathing apparatus is unacceptable because service life will be reduced substantially. Special training in the use of this type of apparatus shall be provided to the wearer (see footnote k).

[m] Protection factor for type and mode of operation as listed above.

Note 1.—Protection factors for respirators, as may be approved by the U.S. Bureau of Mines/National Institute for Occupational Safety and Health (NIOSH) according to applicable approvals for respirators for type and mode of use to protect against airborne radionuclides, may be used to the extent that they do not exceed the protection factors listed in this table. The protection factors listed in this table may not be appropriate to circumstances where chemical or other respiratory hazards exist in addition to radiological hazards. The selection and use of respirators for these circumstances should take into account applicable approvals of the U.S. Bureau of Mines/NIOSH.

Note. 2—Radioactive contaminants for which the concentration values in Table 1, column 1, Appendix B of this part are based on internal dose due to inhalation may, in addition, present external exposure hazards at higher concentrations. Under these circumstances, limitations on occupancy may have to be governed by external dose limits.

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APPENDIX B

Concentrations in Air and Water Above Natural Background

[See notes at end of appendix]

Element (atomic number)	Isotope [1]		Table I		Table II	
		†	Column 1 Air (μCi/ml)	Column 2 Water (μCi/ml)	Column 1 Air (μCi/ml)	Column 2 Water (μCi/ml)
Actinium (89)	Ac 227	S	2×10^{-12}	6×10^{-5}	8×10^{-14}	2×10^{-6}
		I	3×10^{-11}	9×10^{-3}	9×10^{-13}	3×10^{-4}
	Ac 228	S	8×10^{-8}	3×10^{-3}	3×10^{-9}	9×10^{-5}
		I	2×10^{-8}	3×10^{-3}	6×10^{-10}	9×10^{-5}
Americium (95)	Am 241	S	6×10^{-12}	1×10^{-4}	2×10^{-13}	4×10^{-6}
		★ I	1×10^{-10}	8×10^{-4}	4×10^{-12}	3×10^{-5}
	Am 242m	S	6×10^{-12}	1×10^{-4}	2×10^{-13}	4×10^{-6}
		I	3×10^{-10}	3×10^{-3}	9×10^{-12}	9×10^{-5}
	Am 242	S	4×10^{-8}	4×10^{-3}	1×10^{-9}	1×10^{-4}
		I	5×10^{-8}	4×10^{-3}	2×10^{-9}	1×10^{-4}
	Am 243	S	6×10^{-12}	1×10^{-4}	2×10^{-13}	4×10^{-6}
		I	1×10^{-10}	8×10^{-4}	4×10^{-12}	3×10^{-5}
	Am 244	S	4×10^{-6}	1×10^{-1}	1×10^{-7}	5×10^{-3}
		I	2×10^{-5}	1×10^{-1}	8×10^{-7}	5×10^{-3}
Antimony (51)	Sb 122	S	2×10^{-7}	8×10^{-4}	6×10^{-9}	3×10^{-5}
		I	1×10^{-7}	8×10^{-4}	5×10^{-9}	3×10^{-5}
	Sb 124	S	2×10^{-7}	7×10^{-4}	5×10^{-9}	2×10^{-5}
		I	2×10^{-8}	7×10^{-4}	7×10^{-10}	2×10^{-5}
	Sb 125	S	5×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
		I	3×10^{-8}	3×10^{-3}	9×10^{-10}	1×10^{-4}
Argon (18)	A 37	Sub[2]	6×10^{-3}	....	1×10^{-4}	
	A 41	Sub	2×10^{-6}	....	4×10^{-8}	
Arsenic (33)	As 73	S	2×10^{-6}	1×10^{-2}	7×10^{-8}	5×10^{-4}
		I	4×10^{-7}	1×10^{-2}	1×10^{-8}	5×10^{-4}
	As 74	S	3×10^{-7}	2×10^{-3}	1×10^{-8}	5×10^{-5}
		I	1×10^{-7}	2×10^{-3}	4×10^{-9}	5×10^{-5}
	As 76	S	1×10^{-7}	6×10^{-4}	4×10^{-9}	2×10^{-5}
		I	1×10^{-7}	6×10^{-4}	3×10^{-9}	2×10^{-5}
	As 77	S	5×10^{-7}	2×10^{-3}	2×10^{-8}	8×10^{-5}
		I	4×10^{-7}	2×10^{-3}	1×10^{-8}	8×10^{-5}
Astatine (85)	At 211	S	7×10^{-9}	5×10^{-5}	2×10^{-10}	2×10^{-6}
		I	3×10^{-8}	2×10^{-3}	1×10^{-9}	7×10^{-5}
Barium (56)	Ba 131	S	1×10^{-6}	5×10^{-3}	4×10^{-8}	2×10^{-4}
		I	4×10^{-7}	5×10^{-3}	1×10^{-8}	2×10^{-4}
	Ba 140	S	1×10^{-7}	8×10^{-4}	4×10^{-9}	3×10^{-5}
		I	4×10^{-8}	7×10^{-4}	1×10^{-9}	2×10^{-5}
Berkelium (97)	Bk 249	S	9×10^{-10}	2×10^{-2}	3×10^{-11}	6×10^{-4}
		I	1×10^{-7}	2×10^{-2}	4×10^{-9}	6×10^{-4}
	Bk 250	S	1×10^{-7}	6×10^{-3}	5×10^{-9}	2×10^{-4}
		I	1×10^{-6}	6×10^{-3}	4×10^{-8}	2×10^{-4}
Beryllium (4)	Be 7	S	6×10^{-6}	5×10^{-2}	2×10^{-7}	2×10^{-3}
		I	1×10^{-6}	5×10^{-2}	4×10^{-8}	2×10^{-3}
Bismuth (83)	Bi 206	S	2×10^{-7}	1×10^{-3}	6×10^{-9}	4×10^{-5}
		I	1×10^{-7}	1×10^{-3}	5×10^{-9}	4×10^{-5}
	Bi 207	S	2×10^{-7}	2×10^{-3}	6×10^{-9}	6×10^{-5}
		I	1×10^{-8}	2×10^{-3}	5×10^{-10}	6×10^{-5}
	Bi 210	S	6×10^{-9}	1×10^{-3}	2×10^{-10}	4×10^{-5}
		I	6×10^{-9}	1×10^{-3}	2×10^{-10}	4×10^{-5}
	Bi 212	S	1×10^{-7}	1×10^{-2}	3×10^{-9}	4×10^{-4}
		I	2×10^{-7}	1×10^{-2}	7×10^{-9}	4×10^{-4}

APPENDIX B

Concentrations in Air and Water Above Natural Background—Continued

[See notes at end of appendix]

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Element (atomic number)	Isotope [1]	†	Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
Bromine (35)	Br 82	S	1×10^{-6}	8×10^{-3}	4×10^{-8}	3×10^{-4}
		I	2×10^{-7}	1×10^{-3}	6×10^{-9}	4×10^{-5}
Cadmium (48)	Cd 109	S	5×10^{-8}	5×10^{-3}	2×10^{-9}	2×10^{-4}
		I	7×10^{-8}	5×10^{-3}	3×10^{-9}	2×10^{-4}
	Cd 115m	S	4×10^{-8}	7×10^{-4}	1×10^{-9}	3×10^{-5}
		I	4×10^{-8}	7×10^{-4}	1×10^{-9}	3×10^{-5}
	Cd 115	S	2×10^{-7}	1×10^{-3}	8×10^{-9}	3×10^{-5}
		I	2×10^{-7}	1×10^{-3}	6×10^{-9}	4×10^{-5}
Calcium (20)	Ca 45	S	3×10^{-8}	3×10^{-4}	1×10^{-9}	9×10^{-6}
		I	1×10^{-7}	5×10^{-3}	4×10^{-9}	2×10^{-4}
	Ca 47	S	2×10^{-7}	1×10^{-3}	6×10^{-9}	5×10^{-5}
		I	2×10^{-7}	1×10^{-3}	6×10^{-9}	3×10^{-5}
Californium (98)	Cf 249	S	2×10^{-12}	1×10^{-4}	5×10^{-14}	4×10^{-6}
		I	1×10^{-10}	7×10^{-4}	3×10^{-12}	2×10^{-5}
	Cf 250	S	5×10^{-12}	4×10^{-4}	2×10^{-13}	1×10^{-5}
		I	1×10^{-10}	7×10^{-4}	3×10^{-12}	3×10^{-5}
	Cf 251	S	2×10^{-12}	1×10^{-4}	6×10^{-14}	4×10^{-6}
		I	1×10^{-10}	8×10^{-4}	3×10^{-12}	3×10^{-5}
	Cf 252	* S	6×10^{-12}	2×10^{-4}	2×10^{-13}	7×10^{-6}
		* I	3×10^{-11}	2×10^{-4}	1×10^{-12}	7×10^{-6}
	Cf 253	S	8×10^{-10}	4×10^{-3}	3×10^{-11}	1×10^{-4}
		I	8×10^{-10}	4×10^{-3}	3×10^{-11}	1×10^{-4}
	Cf 254	S	5×10^{-12}	4×10^{-6}	2×10^{-13}	1×10^{-7}
		I	5×10^{-12}	4×10^{-6}	2×10^{-13}	1×10^{-7}
Carbon (6)	C 14	S	4×10^{-6}	2×10^{-2}	1×10^{-7}	8×10^{-4}
	(CO_2)	Sub	5×10^{-5}		1×10^{-6}	
Cerium (58)	Ce 141	S	4×10^{-7}	3×10^{-3}	2×10^{-8}	9×10^{-5}
		I	2×10^{-7}	3×10^{-3}	5×10^{-9}	9×10^{-5}
	Ce 143	S	3×10^{-7}	1×10^{-3}	9×10^{-9}	4×10^{-5}
		I	2×10^{-7}	1×10^{-3}	7×10^{-9}	4×10^{-5}
	Ce 144	S	1×10^{-8}	3×10^{-4}	3×10^{-10}	1×10^{-5}
		I	6×10^{-9}	3×10^{-4}	2×10^{-10}	1×10^{-5}
Cesium (55)	Cs 131	S	1×10^{-5}	7×10^{-2}	4×10^{-7}	2×10^{-3}
		I	3×10^{-6}	3×10^{-2}	1×10^{-7}	9×10^{-4}
	Cs 134m	S	4×10^{-5}	2×10^{-1}	1×10^{-6}	6×10^{-3}
		I	6×10^{-6}	3×10^{-2}	2×10^{-7}	1×10^{-3}
	Cs 134	S	4×10^{-8}	3×10^{-4}	1×10^{-9}	9×10^{-6}
		I	1×10^{-8}	1×10^{-3}	4×10^{-10}	4×10^{-5}
	Cs 135	S	5×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
		I	9×10^{-8}	7×10^{-3}	3×10^{-9}	2×10^{-4}
	Cs 136	S	4×10^{-7}	2×10^{-3}	1×10^{-8}	9×10^{-5}
		I	2×10^{-7}	2×10^{-3}	6×10^{-9}	6×10^{-5}
	Cs 137	S	6×10^{-8}	4×10^{-4}	2×10^{-9}	2×10^{-5}
		I	1×10^{-8}	1×10^{-3}	5×10^{-10}	4×10^{-5}
Chlorine (17)	Cl 36	S	4×10^{-7}	2×10^{-3}	1×10^{-8}	8×10^{-5}
		I	2×10^{-8}	2×10^{-3}	8×10^{-10}	6×10^{-5}
	Cl 38	S	3×10^{-6}	1×10^{-2}	9×10^{-8}	4×10^{-4}
		I	2×10^{-6}	1×10^{-2}	7×10^{-8}	4×10^{-4}
Chromium (24)	Cr 51	S	1×10^{-5}	5×10^{-2}	4×10^{-7}	2×10^{-3}
		I	2×10^{-6}	5×10^{-2}	8×10^{-8}	2×10^{-3}

APPENDIX B

Concentrations in Air and Water Above Natural Background—Continued

[See notes at end of appendix]

Element (atomic number)	Isotope [1]	†	Table I		Table II	
			Column 1 Air (μCi/ml)	Column 2 Water (μCi/ml)	Column 1 Air (μCi/ml)	Column 2 Water (μCi/ml)
Cobalt (27)	Co 57	S	3×10^{-6}	2×10^{-2}	1×10^{-7}	5×10^{-4}
		I	2×10^{-7}	1×10^{-2}	6×10^{-9}	4×10^{-4}
	Co 58m	S	2×10^{-5}	8×10^{-2}	6×10^{-7}	3×10^{-3}
		I	9×10^{-6}	6×10^{-2}	3×10^{-7}	2×10^{-3}
	Co 58	S	8×10^{-7}	4×10^{-3}	3×10^{-8}	1×10^{-4}
		I	5×10^{-8}	3×10^{-3}	2×10^{-9}	9×10^{-5}
	Co 60	S	3×10^{-7}	1×10^{-3}	1×10^{-8}	5×10^{-5}
		I	9×10^{-9}	1×10^{-3}	3×10^{-10}	3×10^{-5}
Copper (29)	Cu 64	S	2×10^{-6}	1×10^{-2}	7×10^{-8}	3×10^{-4}
		I	1×10^{-6}	6×10^{-3}	4×10^{-8}	2×10^{-4}
Curium (96)	Cm 242	S	1×10^{-10}	7×10^{-4}	4×10^{-12}	2×10^{-5}
		* I	2×10^{-10}	7×10^{-4}	6×10^{-12}	2×10^{-5}
	Cm 243	S	6×10^{-12}	1×10^{-4}	2×10^{-13}	5×10^{-6}
		I	1×10^{-10}	7×10^{-4}	3×10^{-12}	2×10^{-5}
	Cm 244	S	9×10^{-12}	2×10^{-4}	3×10^{-13}	7×10^{-6}
		I	1×10^{-10}	8×10^{-4}	3×10^{-12}	3×10^{-5}
	Cm 245	S	5×10^{-12}	1×10^{-4}	2×10^{-13}	4×10^{-6}
		I	1×10^{-10}	8×10^{-4}	4×10^{-12}	3×10^{-5}
	Cm 246	S	5×10^{-12}	1×10^{-4}	2×10^{-13}	4×10^{-6}
		I	1×10^{-10}	8×10^{-4}	4×10^{-12}	3×10^{-5}
	Cm 247	S	5×10^{-12}	1×10^{-4}	2×10^{-13}	4×10^{-6}
		I	1×10^{-10}	6×10^{-4}	4×10^{-12}	2×10^{-5}
	Cm 248	S	6×10^{-13}	1×10^{-5}	2×10^{-14}	4×10^{-7}
		I	1×10^{-11}	4×10^{-5}	4×10^{-13}	1×10^{-6}
	Cm 249	S	1×10^{-5}	6×10^{-2}	4×10^{-7}	2×10^{-3}
		I	1×10^{-5}	6×10^{-2}	4×10^{-7}	2×10^{-3}
Dysprosium (66)	Dy 165	S	3×10^{-6}	1×10^{-2}	9×10^{-8}	4×10^{-4}
		I	2×10^{-6}	1×10^{-2}	7×10^{-8}	4×10^{-4}
	Dy 166	S	2×10^{-7}	1×10^{-3}	8×10^{-9}	4×10^{-5}
		I	2×10^{-7}	1×10^{-3}	7×10^{-9}	4×10^{-5}
Einsteinium (99)	Es 253	S	8×10^{-10}	7×10^{-4}	3×10^{-11}	2×10^{-5}
		I	6×10^{-10}	7×10^{-4}	2×10^{-11}	2×10^{-5}
	Es 254m	S	5×10^{-9}	5×10^{-4}	2×10^{-10}	2×10^{-5}
		I	6×10^{-9}	5×10^{-4}	2×10^{-10}	2×10^{-5}
	Es 254	S	2×10^{-11}	4×10^{-4}	6×10^{-13}	1×10^{-5}
		I	1×10^{-10}	4×10^{-4}	4×10^{-12}	1×10^{-5}
	Es 255	S	5×10^{-10}	8×10^{-4}	2×10^{-11}	3×10^{-5}
		I	4×10^{-10}	8×10^{-4}	1×10^{-11}	3×10^{-5}
Erbium (68)	Er 169	S	6×10^{-7}	3×10^{-3}	2×10^{-8}	9×10^{-5}
		I	4×10^{-7}	3×10^{-3}	1×10^{-8}	9×10^{-5}
	Er 171	S	7×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
		I	6×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
Europium (63)	Eu 152	S	4×10^{-7}	2×10^{-3}	1×10^{-8}	6×10^{-5}
	(T/2 = 9.2 hrs)	I	3×10^{-7}	2×10^{-3}	1×10^{-8}	6×10^{-5}
	Eu 152	S	1×10^{-8}	2×10^{-3}	4×10^{-10}	8×10^{-5}
	(T/2 = 13 yrs)	I	2×10^{-8}	2×10^{-3}	6×10^{-10}	8×10^{-5}
	Eu 154	S	4×10^{-9}	6×10^{-4}	1×10^{-10}	2×10^{-5}
		I	7×10^{-9}	6×10^{-4}	2×10^{-10}	2×10^{-5}
	Eu 155	S	9×10^{-8}	6×10^{-3}	3×10^{-9}	2×10^{-4}
		I	7×10^{-8}	6×10^{-3}	3×10^{-9}	2×10^{-4}

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Concentrations in Air and Water Above Natural Background—Continued

[See notes at end of appendix]

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Element (atomic number)	Isotope [1]	†	Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
Fermium (100)	Fm 254	S	6×10^{-8}	4×10^{-3}	2×10^{-9}	1×10^{-4}
		I	7×10^{-8}	4×10^{-3}	2×10^{-9}	1×10^{-4}
	Fm 255	S	2×10^{-8}	1×10^{-3}	6×10^{-10}	3×10^{-5}
		I	1×10^{-8}	1×10^{-3}	4×10^{-10}	3×10^{-5}
	Fm 256	S	3×10^{-9}	3×10^{-5}	1×10^{-10}	9×10^{-7}
		I	2×10^{-9}	3×10^{-5}	6×10^{-11}	9×10^{-7}
Fluorine (9)	F 18	S	5×10^{-6}	2×10^{-2}	2×10^{-7}	8×10^{-4}
		I	3×10^{-6}	1×10^{-2}	9×10^{-8}	5×10^{-4}
Gadolinium (64)	Gd 153	S	2×10^{-7}	6×10^{-3}	8×10^{-9}	2×10^{-4}
		I	9×10^{-8}	6×10^{-3}	3×10^{-9}	2×10^{-4}
	Gd 159	S	5×10^{-7}	2×10^{-3}	2×10^{-8}	8×10^{-5}
		I	4×10^{-7}	2×10^{-3}	1×10^{-8}	8×10^{-5}
Gallium (31)	Ga 72	S	2×10^{-7}	1×10^{-3}	8×10^{-9}	4×10^{-5}
		I	2×10^{-7}	1×10^{-3}	6×10^{-9}	4×10^{-5}
Germanium (32)	Ge 71	S	1×10^{-5}	5×10^{-2}	4×10^{-7}	2×10^{-3}
		I	6×10^{-6}	5×10^{-2}	2×10^{-7}	2×10^{-3}
Gold (79)	Au 196	S	1×10^{-6}	5×10^{-3}	4×10^{-8}	2×10^{-4}
		I	6×10^{-7}	4×10^{-3}	2×10^{-8}	1×10^{-4}
	Au 198	S	3×10^{-7}	2×10^{-3}	1×10^{-8}	5×10^{-5}
		I	2×10^{-7}	1×10^{-3}	8×10^{-9}	5×10^{-5}
	Au 199	S	1×10^{-6}	5×10^{-3}	4×10^{-8}	2×10^{-4}
		I	8×10^{-7}	4×10^{-3}	3×10^{-8}	2×10^{-4}
Hafnium (72)	Hf 181	S	4×10^{-8}	2×10^{-3}	1×10^{-9}	7×10^{-5}
		I	7×10^{-8}	2×10^{-3}	3×10^{-9}	7×10^{-5}
Holmium (67)	Ho 166	S	2×10^{-7}	9×10^{-4}	7×10^{-9}	3×10^{-5}
		I	2×10^{-7}	9×10^{-4}	6×10^{-9}	3×10^{-5}
Hydrogen (1)	H3	S	5×10^{-6}	1×10^{-1}	2×10^{-7}	3×10^{-3}
		I	5×10^{-6}	1×10^{-1}	2×10^{-7}	3×10^{-3}
		Sub	2×10^{-3}		4×10^{-5}	
Indium (49)	In 113m	S	8×10^{-6}	4×10^{-2}	3×10^{-7}	1×10^{-3}
		I	7×10^{-6}	4×10^{-2}	2×10^{-7}	1×10^{-3}
	In 114m	S	1×10^{-7}	5×10^{-4}	4×10^{-9}	2×10^{-5}
		I	2×10^{-8}	5×10^{-4}	7×10^{-10}	2×10^{-5}
	In 115m	S	2×10^{-6}	1×10^{-2}	8×10^{-8}	4×10^{-4}
		I	2×10^{-6}	1×10^{-2}	6×10^{-8}	4×10^{-4}
	In 115	S	2×10^{-7}	3×10^{-3}	9×10^{-9}	9×10^{-5}
		I	3×10^{-8}	3×10^{-3}	1×10^{-9}	9×10^{-5}
Iodine (53)	I 125	S	5×10^{-9}	4×10^{-5}	8×10^{-11}	2×10^{-7}
		I	2×10^{-7}	6×10^{-3}	6×10^{-9}	2×10^{-4}
	I 126	S	8×10^{-9}	5×10^{-5}	9×10^{-11}	3×10^{-7}
		I	3×10^{-7}	3×10^{-3}	1×10^{-8}	9×10^{-5}
	I 129	S	2×10^{-9}	1×10^{-5}	2×10^{-11}	6×10^{-8}
		I	7×10^{-8}	6×10^{-3}	2×10^{-9}	2×10^{-4}
	I 131	S	9×10^{-9}	6×10^{-5}	1×10^{-10}	3×10^{-7}
		I	3×10^{-7}	2×10^{-3}	1×10^{-8}	6×10^{-5}
	I 132	S	2×10^{-7}	2×10^{-3}	3×10^{-9}	8×10^{-6}
		I	9×10^{-7}	5×10^{-3}	3×10^{-8}	2×10^{-4}
	I 133	S	3×10^{-8}	2×10^{-4}	4×10^{-10}	1×10^{-6}
		I	2×10^{-7}	1×10^{-3}	7×10^{-9}	4×10^{-5}
	I 134	S	5×10^{-7}	4×10^{-3}	6×10^{-9}	2×10^{-5}

APPENDIX B

Concentrations in Air and Water Above Natural Background—Continued

[See notes at end of appendix]

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Element (atomic number)	Isotope [1]	†	Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
Iodine (53)	I 134	I	3×10^{-6}	2×10^{-2}	1×10^{-7}	6×10^{-4}
	I 135	S	1×10^{-7}	7×10^{-4}	1×10^{-9}	4×10^{-6}
		I	4×10^{-7}	2×10^{-3}	1×10^{-8}	7×10^{-5}
Iridium (77)	Ir 190	S	1×10^{-6}	6×10^{-3}	4×10^{-8}	2×10^{-4}
		I	4×10^{-7}	5×10^{-3}	1×10^{-8}	2×10^{-4}
	Ir 192	S	1×10^{-7}	1×10^{-3}	4×10^{-9}	4×10^{-5}
		I	3×10^{-8}	1×10^{-3}	9×10^{-10}	4×10^{-5}
	Ir 194	S	2×10^{-7}	1×10^{-3}	8×10^{-9}	3×10^{-5}
		I	2×10^{-7}	9×10^{-4}	5×10^{-9}	3×10^{-5}
Iron (26)	Fe 55	S	9×10^{-7}	2×10^{-2}	3×10^{-8}	8×10^{-4}
		I	1×10^{-6}	7×10^{-2}	3×10^{-8}	2×10^{-3}
	Fe 59	S	1×10^{-7}	2×10^{-3}	5×10^{-9}	6×10^{-5}
		I	5×10^{-8}	2×10^{-3}	2×10^{-9}	5×10^{-5}
Krypton (36)	Kr 85m	Sub	6×10^{-6}	....	1×10^{-7}	....
	Kr 85	Sub	1×10^{-5}	....	3×10^{-7}	....
	Kr 87	Sub	1×10^{-6}	....	2×10^{-8}	....
	Kr 88	Sub	1×10^{-6}	....	2×10^{-8}	....
Lanthanum (57)	La 140	S	2×10^{-7}	7×10^{-4}	5×10^{-9}	2×10^{-5}
		I	1×10^{-7}	7×10^{-4}	4×10^{-9}	2×10^{-5}
Lead (82)	Pb 203	S	3×10^{-6}	1×10^{-2}	9×10^{-8}	4×10^{-4}
		I	2×10^{-6}	1×10^{-2}	6×10^{-8}	4×10^{-4}
	Pb 210	S	1×10^{-10}	4×10^{-6}	4×10^{-12}	1×10^{-7}
		I	2×10^{-10}	5×10^{-3}	8×10^{-12}	2×10^{-4}
	Pb 212	S	2×10^{-8}	6×10^{-4}	6×10^{-10}	2×10^{-5}
		I	2×10^{-8}	5×10^{-4}	7×10^{-10}	2×10^{-5}
Lutetium (71)	Lu 177	S	6×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
		I	5×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
Manganese (25)	Mn 52	S	2×10^{-7}	1×10^{-3}	7×10^{-9}	3×10^{-5}
		I	1×10^{-7}	9×10^{-4}	5×10^{-9}	3×10^{-5}
	Mn 54	* S	4×10^{-7}	4×10^{-3}	1×10^{-8}	1×10^{-4}
		I	4×10^{-8}	3×10^{-3}	1×10^{-9}	1×10^{-4}
	Mn 56	S	8×10^{-7}	4×10^{-3}	3×10^{-8}	1×10^{-4}
		I	5×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
Mercury (80)	Hg 197m	S	7×10^{-7}	6×10^{-3}	3×10^{-8}	2×10^{-4}
		I	8×10^{-7}	5×10^{-3}	3×10^{-8}	2×10^{-4}
	Hg 197	S	1×10^{-6}	9×10^{-3}	4×10^{-8}	3×10^{-4}
		I	3×10^{-6}	1×10^{-2}	9×10^{-8}	5×10^{-4}
	Hg 203	S	7×10^{-8}	5×10^{-4}	2×10^{-9}	2×10^{-5}
		I	1×10^{-7}	3×10^{-3}	4×10^{-9}	1×10^{-4}
Molybdenum (42)	Mo 99	S	7×10^{-7}	5×10^{-3}	3×10^{-8}	2×10^{-4}
		I	2×10^{-7}	1×10^{-3}	7×10^{-9}	4×10^{-5}
Neodymium (60)	Nd 144	S	8×10^{-11}	2×10^{-3}	3×10^{-12}	7×10^{-5}
		I	3×10^{-10}	2×10^{-3}	1×10^{-11}	8×10^{-5}
	Nd 147	S	4×10^{-7}	2×10^{-3}	1×10^{-8}	6×10^{-5}
		I	2×10^{-7}	2×10^{-3}	8×10^{-9}	6×10^{-5}
	Nd 149	S	2×10^{-6}	8×10^{-3}	6×10^{-8}	3×10^{-4}
		I	1×10^{-6}	8×10^{-3}	5×10^{-8}	3×10^{-4}

APPENDIX B

Concentrations in Air and Water Above Natural Background—Continued

[See notes at end of appendix]

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Element (atomic number)	Isotope [1]	†	Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
Neptunium (93)	Np 237	S	4×10^{-12}	9×10^{-5}	1×10^{-13}	3×10^{-6}
		I	1×10^{-10}	9×10^{-4}	4×10^{-12}	3×10^{-5}
	Np 239	S	8×10^{-7}	4×10^{-3}	3×10^{-8}	1×10^{-4}
		I	7×10^{-7}	4×10^{-3}	2×10^{-8}	1×10^{-4}
Nickel (28)	Ni 59	S	5×10^{-7}	6×10^{-3}	2×10^{-8}	2×10^{-4}
		I	8×10^{-7}	6×10^{-2}	3×10^{-8}	2×10^{-3}
	Ni 63	S	6×10^{-8}	8×10^{-4}	2×10^{-9}	3×10^{-5}
		I	3×10^{-7}	2×10^{-2}	1×10^{-8}	7×10^{-4}
	Ni 65	S	9×10^{-7}	4×10^{-3}	3×10^{-8}	1×10^{-4}
		I	5×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
Niobium (Columbium) (41).	Nb 93m	S	1×10^{-7}	1×10^{-2}	4×10^{-9}	4×10^{-4}
		I	2×10^{-7}	1×10^{-2}	5×10^{-9}	4×10^{-4}
	Nb 95	S	5×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
		I	1×10^{-7}	3×10^{-3}	3×10^{-9}	1×10^{-4}
	Nb 97	S	6×10^{-6}	3×10^{-2}	2×10^{-7}	9×10^{-4}
		I	5×10^{-6}	3×10^{-2}	2×10^{-7}	9×10^{-4}
Osmium (76)	Os 185	S	5×10^{-7}	2×10^{-3}	2×10^{-8}	7×10^{-5}
		I	5×10^{-8}	2×10^{-3}	2×10^{-9}	7×10^{-5}
	Os 191m	S	2×10^{-5}	7×10^{-2}	6×10^{-7}	3×10^{-3}
		I	9×10^{-6}	7×10^{-2}	3×10^{-7}	2×10^{-3}
	Os 191	S	1×10^{-6}	5×10^{-3}	4×10^{-8}	2×10^{-4}
		I	4×10^{-7}	5×10^{-3}	1×10^{-8}	2×10^{-4}
	Os 193	S	4×10^{-7}	2×10^{-3}	1×10^{-8}	6×10^{-5}
		I	3×10^{-7}	2×10^{-3}	9×10^{-9}	5×10^{-5}
Palladium (46)	Pd 103	S	1×10^{-6}	1×10^{-2}	5×10^{-8}	3×10^{-4}
		I	7×10^{-7}	8×10^{-3}	3×10^{-8}	3×10^{-4}
	Pd 109	S	6×10^{-7}	3×10^{-3}	2×10^{-8}	9×10^{-5}
		I	4×10^{-7}	2×10^{-3}	1×10^{-8}	7×10^{-5}
Phosphorus (15)	P 32	S	7×10^{-8}	5×10^{-4}	2×10^{-9}	2×10^{-5}
		I	8×10^{-8}	7×10^{-4}	3×10^{-9}	2×10^{-5}
Platinum (78)	Pt 191	S	8×10^{-7}	4×10^{-3}	3×10^{-8}	1×10^{-4}
		I	6×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
	Pt 193m	S	7×10^{-6}	3×10^{-2}	2×10^{-7}	1×10^{-3}
		I	5×10^{-6}	3×10^{-2}	2×10^{-7}	1×10^{-3}
*	Pt 193	S	1×10^{-6}	3×10^{-2}	4×10^{-8}	9×10^{-4}
		I	3×10^{-7}	5×10^{-2}	1×10^{-8}	2×10^{-3}
	Pt 197m	S	6×10^{-6}	3×10^{-2}	2×10^{-7}	1×10^{-3}
		I	5×10^{-6}	3×10^{-2}	2×10^{-7}	9×10^{-4}
	Pt 197	S	8×10^{-7}	4×10^{-3}	3×10^{-8}	1×10^{-4}
		I	6×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
Plutonium (94)	Pu 238	S	2×10^{-12}	1×10^{-4}	7×10^{-14}	5×10^{-6}
		I	3×10^{-11}	8×10^{-4}	1×10^{-12}	3×10^{-5}
	Pu 239	S	2×10^{-12}	1×10^{-4}	6×10^{-14}	5×10^{-6}
		I	4×10^{-11}	8×10^{-4}	1×10^{-12}	3×10^{-5}
	Pu 240	S	2×10^{-12}	1×10^{-4}	6×10^{-14}	5×10^{-6}
		I	4×10^{-11}	8×10^{-4}	1×10^{-12}	3×10^{-5}
	Pu 241	S	9×10^{-11}	7×10^{-3}	3×10^{-12}	2×10^{-4}
		I	4×10^{-8}	4×10^{-2}	1×10^{-9}	1×10^{-3}

APPENDIX B

Concentrations in Air and Water Above Natural Background—Continued

[See notes at end of appendix]

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Element (atomic number)	Isotope[1]	†	Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
Plutonium (94)	Pu 242	S	2×10^{-12}	1×10^{-4}	6×10^{-14}	5×10^{-6}
		I	4×10^{-11}	9×10^{-4}	1×10^{-12}	3×10^{-5}
	Pu 243	S	2×10^{-6}	1×10^{-2}	6×10^{-8}	3×10^{-4}
		I	2×10^{-6}	1×10^{-2}	8×10^{-8}	3×10^{-4}
	Pu 244	S	2×10^{-12}	1×10^{-4}	6×10^{-14}	4×10^{-6}
		I	3×10^{-11}	3×10^{-4}	1×10^{-12}	1×10^{-5}
Polonium (84)	Po 210	S	5×10^{-10}	2×10^{-5}	2×10^{-11}	7×10^{-7}
		I	2×10^{-10}	8×10^{-4}	7×10^{-12}	3×10^{-5}
Potassium (19)	K 42	S	2×10^{-6}	9×10^{-3}	7×10^{-8}	3×10^{-4}
		I	1×10^{-7}	6×10^{-4}	4×10^{-9}	2×10^{-5}
Praseodymium (59)	Pr 142	S	2×10^{-7}	9×10^{-4}	7×10^{-9}	3×10^{-5}
		I	2×10^{-7}	9×10^{-4}	5×10^{-9}	3×10^{-5}
	Pr 143	S	3×10^{-7}	1×10^{-3}	1×10^{-8}	5×10^{-5}
		I	2×10^{-7}	1×10^{-3}	6×10^{-9}	5×10^{-5}
Promethium (61)	Pm 147	S	6×10^{-8}	6×10^{-3}	2×10^{-9}	2×10^{-4}
		I	1×10^{-7}	6×10^{-3}	3×10^{-9}	2×10^{-4}
	Pm 149	S	3×10^{-7}	1×10^{-3}	1×10^{-8}	4×10^{-5}
		I	2×10^{-7}	1×10^{-3}	8×10^{-9}	4×10^{-5}
Protoactinium (91)	Pa 230	S	2×10^{-9}	7×10^{-3}	6×10^{-11}	2×10^{-4}
		I	8×10^{-10}	7×10^{-3}	3×10^{-11}	2×10^{-4}
	Pa 231	S	1×10^{-12}	3×10^{-5}	4×10^{-14}	9×10^{-7}
		I	1×10^{-10}	8×10^{-4}	4×10^{-12}	2×10^{-5}
	Pa 233	S	6×10^{-7}	4×10^{-3}	2×10^{-8}	1×10^{-4}
		I	2×10^{-7}	3×10^{-3}	6×10^{-9}	1×10^{-4}
Radium (88)	Ra 223	S	2×10^{-9}	2×10^{-5}	6×10^{-11}	7×10^{-7}
		I	2×10^{-10}	1×10^{-4}	8×10^{-12}	4×10^{-6}
	Ra 224	S	5×10^{-9}	7×10^{-5}	2×10^{-10}	2×10^{-6}
		I	7×10^{-10}	2×10^{-4}	2×10^{-11}	5×10^{-6}
	Ra 226	S	3×10^{-11}	4×10^{-7}	3×10^{-12}	3×10^{-8}
		I	5×10^{-11}	9×10^{-4}	2×10^{-12}	3×10^{-5}
	Ra 228	S	7×10^{-11}	8×10^{-7}	2×10^{-12}	3×10^{-8}
		I	4×10^{-11}	7×10^{-4}	1×10^{-12}	3×10^{-5}
Radon (86)	Rn 220	S	3×10^{-7}		1×10^{-8}	
	Rn 222[3] ...		... 3×10^{-8}		3×10^{-9}	
Rhenium (75)	Re 183	S	3×10^{-6}	2×10^{-2}	9×10^{-8}	6×10^{-4}
		I	2×10^{-7}	8×10^{-3}	5×10^{-9}	3×10^{-4}
	Re 186	S	6×10^{-7}	3×10^{-3}	2×10^{-8}	9×10^{-5}
		I	2×10^{-7}	1×10^{-3}	8×10^{-9}	5×10^{-5}
	Re 187	S	9×10^{-6}	7×10^{-2}	3×10^{-7}	3×10^{-3}
		I	5×10^{-7}	4×10^{-2}	2×10^{-8}	2×10^{-3}
	Re 188	S	4×10^{-7}	2×10^{-3}	1×10^{-8}	6×10^{-5}
		I	2×10^{-7}	9×10^{-4}	6×10^{-9}	3×10^{-5}
Rhodium (45)	Rh 103m	S	8×10^{-5}	4×10^{-1}	3×10^{-6}	1×10^{-2}
		I	6×10^{-5}	3×10^{-1}	2×10^{-6}	1×10^{-2}
	Rh 105	S	8×10^{-7}	4×10^{-3}	3×10^{-8}	1×10^{-4}
		I	5×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
Rubidium (37)	Rb 86	S	3×10^{-7}	2×10^{-3}	1×10^{-8}	7×10^{-5}
		I	7×10^{-8}	7×10^{-4}	2×10^{-9}	2×10^{-5}
	Rb 87	S	5×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
		I	7×10^{-8}	5×10^{-3}	2×10^{-9}	2×10^{-4}

APPENDIX B

Concentrations in Air and Water Above Natural Background—Continued

[See notes at end of appendix]

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Element (atomic number)	Isotope [1]	†	Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
Ruthenium (44)	Ru 97	S	2×10^{-6}	1×10^{-2}	8×10^{-8}	4×10^{-4}
		I	2×10^{-6}	1×10^{-2}	6×10^{-8}	3×10^{-4}
	Ru 103	S	5×10^{-7}	2×10^{-3}	2×10^{-8}	8×10^{-5}
		I	8×10^{-8}	2×10^{-3}	3×10^{-9}	8×10^{-5}
	Ru 105	S	7×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
		I	5×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
	Ru 106	S	8×10^{-8}	4×10^{-4}	3×10^{-9}	1×10^{-5}
		I	6×10^{-9}	3×10^{-4}	2×10^{-10}	1×10^{-5}
Samarium (62)	Sm 147	S	7×10^{-11}	2×10^{-3}	2×10^{-12}	6×10^{-5}
		I	3×10^{-10}	2×10^{-3}	9×10^{-12}	7×10^{-5}
	Sm 151	S	6×10^{-8}	1×10^{-2}	2×10^{-9}	4×10^{-4}
		I	1×10^{-7}	1×10^{-2}	5×10^{-9}	4×10^{-4}
	Sm 153	S	5×10^{-7}	2×10^{-3}	2×10^{-8}	8×10^{-5}
		I	4×10^{-7}	2×10^{-3}	1×10^{-8}	8×10^{-5}
Scandium (21)	Sc 46	S	2×10^{-7}	1×10^{-3}	8×10^{-9}	4×10^{-5}
		I	2×10^{-8}	1×10^{-3}	8×10^{-10}	4×10^{-5}
	Sc 47	S	6×10^{-7}	3×10^{-3}	2×10^{-8}	9×10^{-5}
		I	5×10^{-7}	3×10^{-3}	2×10^{-8}	9×10^{-5}
	Sc 48	S	2×10^{-7}	8×10^{-4}	6×10^{-9}	3×10^{-5}
		I	1×10^{-7}	8×10^{-4}	5×10^{-9}	3×10^{-5}
Selenium (34)	Se 75	S	1×10^{-6}	9×10^{-3}	4×10^{-8}	3×10^{-4}
		I	1×10^{-7}	8×10^{-3}	4×10^{-9}	3×10^{-4}
Silicon (14)	Si 31	S	6×10^{-6}	3×10^{-2}	2×10^{-7}	9×10^{-4}
		I	1×10^{-6}	6×10^{-3}	3×10^{-8}	2×10^{-4}
Silver (47)	Ag 105	S	6×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
		I	8×10^{-8}	3×10^{-3}	3×10^{-9}	1×10^{-4}
	Ag 110m	S	2×10^{-7}	9×10^{-4}	7×10^{-9}	3×10^{-5}
		I	1×10^{-8}	9×10^{-4}	3×10^{-10}	3×10^{-5}
	Ag 111	S	3×10^{-7}	1×10^{-3}	1×10^{-8}	4×10^{-5}
		I	2×10^{-7}	1×10^{-3}	8×10^{-9}	4×10^{-5}
Sodium (11)	Na 22	S	2×10^{-7}	1×10^{-3}	6×10^{-9}	4×10^{-5}
		I	9×10^{-9}	9×10^{-4}	3×10^{-10}	3×10^{-5}
	Na 24	S	1×10^{-6}	6×10^{-3}	4×10^{-8}	2×10^{-4}
		I	1×10^{-7}	8×10^{-4}	5×10^{-9}	3×10^{-5}
Strontium (38)	Sr 85m	S	4×10^{-5}	2×10^{-1}	1×10^{-6}	7×10^{-3}
		I	3×10^{-5}	2×10^{-1}	1×10^{-6}	7×10^{-3}
	Sr 85	S	2×10^{-7}	3×10^{-3}	8×10^{-9}	1×10^{-4}
		I	1×10^{-7}	5×10^{-3}	4×10^{-9}	2×10^{-4}
	Sr 89	S	3×10^{-8}	3×10^{-4}	3×10^{-10}	3×10^{-6}
		I	4×10^{-8}	8×10^{-4}	1×10^{-9}	3×10^{-5}
	Sr 90	S	1×10^{-9}	1×10^{-5}	3×10^{-11}	3×10^{-7}
		I	5×10^{-9}	1×10^{-3}	2×10^{-10}	4×10^{-5}
	Sr 91	S	4×10^{-7}	2×10^{-3}	2×10^{-8}	7×10^{-5}
		I	3×10^{-7}	1×10^{-3}	9×10^{-9}	5×10^{-5}
	Sr 92	S	4×10^{-7}	2×10^{-3}	2×10^{-8}	7×10^{-5}
		I	3×10^{-7}	2×10^{-3}	1×10^{-8}	6×10^{-5}
Sulfur (16)	S 35	S	3×10^{-7}	2×10^{-3}	9×10^{-9}	6×10^{-5}
		I	3×10^{-7}	8×10^{-3}	9×10^{-9}	3×10^{-4}
Tantalum (73)	Ta 182	S	4×10^{-8}	1×10^{-3}	1×10^{-9}	4×10^{-5}
		I	2×10^{-8}	1×10^{-3}	7×10^{-10}	4×10^{-5}

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Concentrations in Air and Water Above Natural Background—Continued

[See notes at end of appendix]

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Element (atomic number)	Isotope [1]	†	Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
Technetium (43)	Tc 96m	S	8×10^{-5}	$4\ 10^{-1}$	3×10^{-6}	1×10^{-2}
		I	3×10^{-5}	3×10^{-1}	1×10^{-6}	1×10^{-2}
	Tc 96	S	6×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
		I	2×10^{-7}	1×10^{-3}	8×10^{-9}	5×10^{-5}
	Tc 97m	S	2×10^{-6}	1×10^{-2}	8×10^{-8}	4×10^{-4}
		I	2×10^{-7}	5×10^{-3}	5×10^{-9}	2×10^{-4}
	Tc 97	S	1×10^{-5}	5×10^{-2}	4×10^{-7}	2×10^{-3}
		I	3×10^{-7}	2×10^{-2}	1×10^{-8}	8×10^{-4}
	Tc 99m	S	4×10^{-5}	2×10^{-1}	1×10^{-6}	6×10^{-3}
		I	1×10^{-5}	8×10^{-2}	5×10^{-7}	3×10^{-3}
	Tc 99	S	2×10^{-6}	1×10^{-2}	7×10^{-8}	3×10^{-4}
		I	6×10^{-8}	5×10^{-3}	2×10^{-9}	2×10^{-4}
Tellurium (52)	Te 125m	S	4×10^{-7}	5×10^{-3}	1×10^{-8}	2×10^{-4}
		I	1×10^{-7}	3×10^{-3}	4×10^{-9}	1×10^{-4}
	Te 127m	S	1×10^{-7}	2×10^{-3}	5×10^{-9}	6×10^{-5}
		I	4×10^{-8}	2×10^{-3}	1×10^{-9}	5×10^{-5}
	Te 127	S	2×10^{-6}	8×10^{-3}	6×10^{-8}	3×10^{-4}
		I	9×10^{-7}	5×10^{-3}	3×10^{-8}	2×10^{-4}
	Te 129m	S	8×10^{-8}	1×10^{-3}	3×10^{-9}	3×10^{-5}
		I	3×10^{-8}	6×10^{-4}	1×10^{-9}	2×10^{-5}
	Te 129	S	5×10^{-6}	2×10^{-2}	2×10^{-7}	8×10^{-4}
		I	4×10^{-6}	2×10^{-2}	1×10^{-7}	8×10^{-4}
	Te 131m	S	4×10^{-7}	2×10^{-3}	1×10^{-8}	6×10^{-5}
		I	2×10^{-7}	1×10^{-3}	6×10^{-9}	4×10^{-5}
	Te 132	S	2×10^{-7}	9×10^{-4}	7×10^{-9}	3×10^{-5}
		I	1×10^{-7}	6×10^{-4}	4×10^{-9}	2×10^{-5}
Terbium (65)	Tb 160	S	1×10^{-7}	1×10^{-3}	3×10^{-9}	4×10^{-5}
		I	3×10^{-8}	1×10^{-3}	1×10^{-9}	4×10^{-5}
Thallium (81)	Tl 200	S	3×10^{-6}	1×10^{-2}	9×10^{-8}	4×10^{-4}
		I	1×10^{-6}	7×10^{-3}	4×10^{-8}	2×10^{-4}
	Tl 201	S	2×10^{-6}	9×10^{-3}	7×10^{-8}	3×10^{-4}
		I	9×10^{-7}	5×10^{-3}	3×10^{-8}	2×10^{-4}
	Tl 202	S	8×10^{-7}	4×10^{-3}	3×10^{-8}	1×10^{-4}
		I	2×10^{-7}	2×10^{-3}	8×10^{-9}	7×10^{-5}
	Tl 204	S	6×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
		I	3×10^{-8}	2×10^{-3}	9×10^{-10}	6×10^{-5}
Thorium (90)	* Th 227	S	3×10^{-10}	5×10^{-4}	1×10^{-11}	2×10^{-5}
		I	2×10^{-10}	5×10^{-4}	6×10^{-12}	2×10^{-5}
	Th 228	S	9×10^{-12}	2×10^{-4}	3×10^{-13}	7×10^{-6}
		I	6×10^{-12}	4×10^{-4}	2×10^{-13}	1×10^{-5}
	Th 230	S	2×10^{-12}	5×10^{-5}	8×10^{-14}	2×10^{-6}
		I	1×10^{-11}	9×10^{-4}	3×10^{-13}	3×10^{-5}
	* Th 231	S	1×10^{-6}	7×10^{-3}	5×10^{-8}	2×10^{-4}
		I	1×10^{-6}	7×10^{-3}	4×10^{-8}	2×10^{-4}
	Th 232	S	3×10^{-11}	5×10^{-5}	1×10^{-12}	2×10^{-6}
		I	3×10^{-11}	1×10^{-3}	1×10^{-12}	4×10^{-5}
	†* Th natural	S	6×10^{-11}	6×10^{-5}	2×10^{-12}	2×10^{-6}
		I	6×10^{-11}	6×10^{-4}	2×10^{-12}	2×10^{-5}

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APPENDIX B

Concentrations in Air and Water Above Natural Background—Continued

[See notes at end of appendix]

—25 FR 10914—

Element (atomic number)	Isotope [1]	†	Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
Thorium (90)	Th 234	S	6×10^{-8}	5×10^{-4}	2×10^{-9}	2×10^{-5}
		I	3×10^{-8}	5×10^{-4}	1×10^{-9}	2×10^{-5}
Thulium (69)	Tm 170	S	4×10^{-8}	1×10^{-3}	1×10^{-9}	5×10^{-5}
		I	3×10^{-8}	1×10^{-3}	1×10^{-9}	3×10^{-5}
	Tm 171	S	1×10^{-7}	1×10^{-2}	4×10^{-9}	5×10^{-4}
		I	2×10^{-7}	1×10^{-2}	8×10^{-9}	5×10^{-4}
Tin (50)	Sn 113	S	4×10^{-7}	2×10^{-3}	1×10^{-8}	9×10^{-5}
		I	5×10^{-8}	2×10^{-3}	2×10^{-9}	8×10^{-5}
	Sn 125	S	1×10^{-7}	5×10^{-4}	4×10^{-9}	2×10^{-5}
		I	8×10^{-8}	5×10^{-4}	3×10^{-9}	2×10^{-5}
Tungsten (Wolfram) (74)	W 181	S	2×10^{-6}	1×10^{-2}	8×10^{-8}	4×10^{-4}
		I	1×10^{-7}	1×10^{-2}	4×10^{-9}	3×10^{-4}
	W 185	S	8×10^{-7}	4×10^{-3}	3×10^{-8}	1×10^{-4}
		I	1×10^{-7}	3×10^{-3}	4×10^{-9}	1×10^{-4}
	W 187	S	4×10^{-7}	2×10^{-3}	2×10^{-8}	7×10^{-5}
		I	3×10^{-7}	2×10^{-3}	1×10^{-8}	6×10^{-5}
Uranium (92)	U 230	S	3×10^{-10}	1×10^{-4}	1×10^{-11}	5×10^{-6}
		I	1×10^{-10}	1×10^{-4}	4×10^{-12}	5×10^{-6}
	U 232	S	1×10^{-10}	8×10^{-4}	3×10^{-12}	3×10^{-5}
		I	3×10^{-11}	8×10^{-4}	9×10^{-13}	3×10^{-5}
	U 233	S	5×10^{-10}	9×10^{-4}	2×10^{-11}	3×10^{-5}
		I	1×10^{-10}	9×10^{-4}	4×10^{-12}	3×10^{-5}
**	U 234	S^4	6×10^{-10}	9×10^{-4}	2×10^{-11}	3×10^{-5}
		I	1×10^{-10}	9×10^{-4}	4×10^{-12}	3×10^{-5}
**	U 235	S^4	5×10^{-10}	8×10^{-4}	2×10^{-11}	3×10^{-5}
		I	1×10^{-10}	8×10^{-4}	4×10^{-12}	3×10^{-5}
	U 236	S	6×10^{-10}	1×10^{-3}	2×10^{-11}	3×10^{-5}
		I	1×10^{-10}	1×10^{-3}	4×10^{-12}	3×10^{-5}
**	U 238	S^4	7×10^{-11}	1×10^{-3}	3×10^{-12}	4×10^{-5}
		I	1×10^{-10}	1×10^{-3}	5×10^{-12}	4×10^{-5}
	U 240	S	2×10^{-7}	1×10^{-3}	8×10^{-9}	3×10^{-5}
		I	2×10^{-7}	1×10^{-3}	6×10^{-9}	3×10^{-5}
**	U-natural	S^4	1×10^{-10}	1×10^{-3}	3×10^{-12}	3×10^{-5}
		I	1×10^{-10}	1×10^{-3}	5×10^{-12}	3×10^{-5}
Vanadium (23)	V 48	S	2×10^{-7}	9×10^{-4}	6×10^{-9}	3×10^{-5}
		I	6×10^{-8}	8×10^{-4}	2×10^{-9}	3×10^{-5}
Xenon (54)	Xe 131m	Sub	2×10^{-5}		4×10^{-7}	
	Xe 133	Sub	1×10^{-5}		3×10^{-7}	
	Xe 133m	Sub	1×10^{-5}		3×10^{-7}	
	Xe 135	Sub	4×10^{-6}		1×10^{-7}	
Ytterbium (70)	Yb 175	S	7×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
		I	6×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
Yttrium (39)	Y 90	S	1×10^{-7}	6×10^{-4}	4×10^{-9}	2×10^{-5}
		I	1×10^{-7}	6×10^{-4}	3×10^{-9}	2×10^{-5}
	Y 91m	S	2×10^{-5}	1×10^{-1}	8×10^{-7}	3×10^{-3}
		I	2×10^{-5}	1×10^{-1}	6×10^{-7}	3×10^{-3}
	Y 91	S	4×10^{-8}	8×10^{-4}	1×10^{-9}	3×10^{-5}
		I	3×10^{-8}	8×10^{-4}	1×10^{-9}	3×10^{-5}
	Y 92	S	4×10^{-7}	2×10^{-3}	1×10^{-8}	6×10^{-5}
		I	3×10^{-7}	2×10^{-3}	1×10^{-8}	6×10^{-5}
	Y 93	S	2×10^{-7}	8×10^{-4}	6×10^{-9}	3×10^{-5}
		I	1×10^{-7}	8×10^{-4}	3×10^{-9}	3×10^{-5}

APPENDIX B

Concentrations in Air and Water Above Natural Background—Continued

25 FR 10914

Element (atomic number)	Isotope [1]		Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
Zinc (30)	Zn 65	S	1×10^{-7}	3×10^{-3}	4×10^{-9}	1×10^{-4}
		I	6×10^{-8}	5×10^{-3}	2×10^{-9}	2×10^{-4}
	Zn 69m	S	4×10^{-7}	2×10^{-3}	1×10^{-8}	7×10^{-5}
		I	3×10^{-7}	2×10^{-3}	1×10^{-8}	6×10^{-5}
	Zn 69	S	7×10^{-6}	5×10^{-2}	2×10^{-7}	2×10^{-3}
		I	9×10^{-6}	5×10^{-2}	3×10^{-7}	2×10^{-3}
Zirconium (40)	Zr 93	S	1×10^{-7}	2×10^{-2}	4×10^{-9}	8×10^{-4}
		I	3×10^{-7}	2×10^{-2}	1×10^{-8}	8×10^{-4}
	Zr 95	S	1×10^{-7}	2×10^{-3}	4×10^{-9}	6×10^{-5}
		I	3×10^{-8}	2×10^{-3}	1×10^{-9}	6×10^{-5}
	Zr 97	S	1×10^{-7}	5×10^{-4}	4×10^{-9}	2×10^{-5}
		I	9×10^{-8}	5×10^{-4}	3×10^{-9}	2×10^{-5}
Any single radionuclide not listed above with decay mode other than alpha emission or spontaneous fission and with radioactive half-life less than 2 hours.		Sub	1×10^{-6}		3×10^{-8}	
Any single radionuclide not listed above with decay mode other than alpha emission or spontaneous fission and with radioactive half-life greater than 2 hours.			3×10^{-9}	9×10^{-5}	1×10^{-10}	3×10^{-6}
Any single radionuclide not listed above, which decays by alpha emission or spontaneous fission.			6×10^{-13}	4×10^{-7}	2×10^{-14}	3×10^{-8}

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[1] Soluble (S); Insoluble (I).

[2] "Sub" means that values given are for submersion in a semispherical infinite cloud of airborne material.

40 FR 50704

[3] These radon concentrations are appropriate for protection from radon-222 combined with its short-lived daughters. Alternatively, the value in Table I may be replaced by one-third (⅓) "working level." (A "working level" is defined as any combination of short-lived radon-222 daughters, polonium-218, lead-214, bismuth-214 and polonium-214, in one liter of air, without regard to the degree of equilibrium, that will result in the ultimate emission of 1.3 x 10^{5} MeV of alpha particle energy.) The Table II value may be replaced by one-thirtieth ($\frac{1}{30}$) of a "working level." The limit on radon-222 concentrations in restricted areas may be based on an annual average.

30 FR 23990

‡4. For soluble mixtures of U-238, U-234 and U-235 in air chemical toxicity may be the limiting factor. If the percent by weight (enrichment) of U-235 is less than 5, the concentration value for a 40-hour workweek, Table I, is 0.2 milligrams uranium per cubic meter of air average. For any enrichment, the product of the average concentration and time of exposure during a 40-hour workweek shall not exceed 8×10^{-10} SA μCi-hr/ml, where SA is the specific activity of the uranium inhaled. The concentration value for Table II is 0.007 milligrams uranium per cubic meter of air. The specific activity for natural uranium is 6.77×10^{-7} curies per gram U. The specific activity for other mixtures of U-238, U-235 and U-234, if not known, shall be:

$$SA=3.6\times10^{-7}\ \text{curies/gram U} \qquad \text{U-depleted}$$
$$SA=(0.4+0.38E+0.0034E^{2})\,10^{-6} \qquad E\geq0.72$$

where E is the percentage by weight of U-235, expressed as percent.

*Amended 37 FR 23319.

**Amended 39 FR 23990; footnote redesignated 40 FR 50704.

***Amended 40 FR 50704.

†Amended 38 FR 29314.

‡Amended 39 FR 25463; redesignated 40 FR 50704.

NOTE TO APPENDIX B

25 FR 10914

NOTE: In any case where there is a mixture in air or water of more than one radionuclide, the limiting values for purposes of this Appendix should be determined as follows:

1. If the identity and concentration of each radionuclide in the mixture are known, the limiting values should be derived as follows: Determine, for each radionuclide in the mixture, the ratio between the quantity present in the mixture and the limit otherwise established in Appendix B for the specific radionuclide when not in a mixture. The sum of such ratios for all the radionuclides in the mixture may not exceed "1" (i.e., "unity").

EXAMPLE: If radionuclides A, B, and C are present in concentrations C_A, C_B, and C_C, and if the applicable MPC's, are MPC_A, and MPC_B, and MPC_C respectively, then the concentrations shall be limited so that the following relationship exists:

$$\frac{C_A}{MPC_A}+\frac{C_B}{MPC_B}+\frac{C_C}{MPC_C}\leq 1$$

30 FR 15801

2. If either the identity or the concentration of any radionuclide in the mixture is not known, the limiting values for purposes of Appendix B shall be:

a. For purposes of Table I, Col. 1—6×10^{-13}

b. For purposes of Table I, Col. 2—4×10^{-7}

c. For purposes of Table II, Col. 1—2×10^{-14}

d. For purposes of Table II, Col. 2—3×10^{-8}

26 FR 11046

3. If any of the conditions specified below are met, the corresponding values specified below may be used in lieu of those specified in paragraph 2 above.

a. If the identity of each radionuclide in the mixture is known but the concentration of one or more of the radionuclides in the mixture is not known, the concentration limit for the mixture is the limit specified in Appendix "B" for the radionuclide in the mixture having the lowest concentration limit; or

b. If the identity of each radionuclide in the mixture is not known, but it is known that certain radionuclides specified in Appendix "B" are not present in the mixture, the concentration limit for the mixture is the lowest concentration limit specified in Appendix "B" for any radionuclide which is not known to be absent from the mixture; or

30 FR 15801

c. Element (atomic number) and isotope	Table I		Table II	
	Column 1 Air (μCi/ml)	Column 2 Water (μCi/ml)	Column 1 Air (μCi/ml)	Column 2 Water (μCi/ml)
If it is known that Sr 90, I 125, I 126, I 129, I 131, (I 133, table II only), Pb 210, Po 210, At 211, Ra 223, Ra 224, Ra 226, Ac 227, Ra 228, Th 230, Pa 231, Th 232, Th-nat, Cm 248, Cf 254, and Fm 256 are not present	....	9×10^{-5}	....	3×10^{-6}
If it is known that Sr 90, I 125, I 126, I 129, (I 131, I 133, table II only), Pb 210, Po 210, Ra 223, Ra 226, Ra 228, Pa 231, Th-nat, Cm 248, Cf 254, and Fm 256 are not present	....	6×10^{-5}	....	2×10^{-6}
If it is known that Sr 90, I 129, (I 125, I 126, I 131, table II only), Pb 210, Ra 226, Ra 228, Cm 248, and Cf 254 are not present	....	2×10^{-4}	....	6×10^{-7}
If it is known that (I 129, table II only), Ra 226, and Ra 228 are not present	....	3×10^{-4}	....	1×10^{-7}
If it is known that alpha-emitters and Sr 90, I 129, Pb 210, Ac 227, Ra 228, Pa 230, Pu 241, and Bk 249 are not present	3×10^{-9}	....	1×10^{-10}	....
If it is known that alpha-emitters and Pb 210, Ac 227, Ra 228, and Pu 241 are not present	3×10^{-10}	....	1×10^{-11}	....
If it is known that alpha-emitters and Ac 227 are not present	3×10^{-11}	....	1×10^{-12}	....
If it is known that Ac 227, Th 230, Pa 231, Pu 238, Pu 239, Pu 240, Pu 242, Pu 244, Cm 248, Cf 249 and Cf 251 are not present	3×10^{-12}	....	1×10^{-13}	....

40 FR 50704

4. If a mixture of radionuclides consists of uranium and its daughters in ore dust prior to chemical separation of the uranium from the ore, the values specified below may be used for uranium and its daughters through radium-226, instead of those from paragraphs 1, 2, or 3 above.

39 FR 23990

a. For purposes of Table I, Col. 1—1×10^{-10} μCi/ml gross alpha activity; or 5×10^{-11} μCi/ml natural uranium; or 75 micrograms per cubic meter of air natural uranium.

b. For purposes of Table II, Col. 1—3×10^{-12} μCi/ml gross alpha activity; or 2×10^{-12} μCi/ml natural uranium; or 3 micrograms per cubic meter of air natural uranium.

26 FR 11046

5. For purposes of this note, a radionuclide may be considered as not present in a mixture if (a) the ratio of the concentration of that radionuclide in the mixture (C_A) to the concentration limit for that radionuclide specified in Table II of Appendix B (MPC_A) does not exceed 1/10 (i.e. $\frac{C_A}{MPC_A}\leq\frac{1}{10}$) and (b) the sum of such ratios for all the radionuclides considered as not present in the mixture does not exceed ¼ (i.e. $\frac{C_A}{MPC_A}+\frac{C_B}{MPC_B}+\cdots\cdots\leq\frac{1}{4}$).

APPENDIX C

Material	Microcuries
Americium-241	.01
Antimony-122	100
Antimony-124	10
Antimony-125	10
Arsenic-73	100
Arsenic-74	10
Arsenic-76	10
Arsenic-77	100
Barium-131	10
*Barium-133	10
Barium-140	10
Bismuth-210	1
Bromine-82	10
Cadmium-109	10
Cadmium-115m	10
Cadmium-115	100
Calcium-45	10
Calcium-47	10
Carbon-14	100
Cerium-141	100
Cerium-143	100
Cerium-144	1
Cesium-131	1,000
Cesium-134m	100
Cesium-134	1
Cesium-135	10
Cesium-136	10
Cesium-137	10
Chlorine-36	10
Chlorine-38	10
Chromium-51	1,000
Cobalt-58m	10
Cobalt-58	10
Cobalt-60	1
Copper-64	100
Dysprosium-165	10
Dysprosium-166	100
Erbium-169	100
Erbium-171	100
Europium-152 9.2 h	100
Europium-152 13 yr	1
Europium-154	1
Europium-155	10
Fluorine-18	1,000
Gadolinium-153	10
Gadolinium-159	100
Gallium-72	10
Germanium-71	100
Gold-198	100
Gold-199	100
Hafnium-181	10
Holmium-166	100
Hydrogen-3	1,000
Indium-113m	100
Indium-114m	10
Indium-115m	100
Indium-115	10
Iodine-125	1
Iodine-126	1
Iodine-129	0.1
Iodine-131	1
Iodine-132	10
Iodine-133	1
Iodine-134	10
Iodine-135	10
Iridium-192	10
Iridium-194	100
Iron-55	100
Iron-59	10
Krypton-85	100
Krypton-87	10
Lanthanum-140	10
Lutetium-177	100
Manganese-52	10
Manganese-54	10
Manganese-56	10
Mercury-197m	100
Mercury-197	100
Mercury-203	10
Molybdenum-99	100
Neodymium-147	100
Neodymium-149	100
Nickel-59	100
Nickel-63	10
Nickel-65	100
Niobium-93m	10
Niobium-95	10
Niobium-97	10
Osmium-185	10
Osmium-191m*	100
Osmium-191	100
Osmium-193	100
Palladium-103	100
Palladium-109	100
Phosphorus-32	10
Platinum-191	100
Platinum-193m	100
Platinum-193	100
Platinum-197m	100
Platinum-197	100
Plutonium-239	.01
Polonium-210	0.1
Potassium-42	10
Praseodymium-142	100
Praseodymium-143	100
Promethium-147	10
Promethium-149	10
Radium-226	.01
Rhenium-186	100
Rhenium-188	100
Rhodium-103m	100
Rhodium-105	100
Rubidium-86	10
Rubidium-87	10
Ruthenium-97	100
Ruthenium-103	10
Ruthenium-105	10
Ruthenium-106	1
Samarium-151	10
Samarium-153	100
Scandium-46	10
Scandium-47	100
Scandium-48	10
Selenium-75	10
Silicon-31	100
Silver-105	10
Silver-110m	1
Silver-111	100
Sodium-24	10
Strontium-85	10
Strontium-89	1
Strontium-90	0.1
Strontium-91	10
Strontium-92	10
Sulphur-35	100
Tantalum-182	10
Technetium-96	10
Technetium-97m	100
Technetium-97	100
Technetium-99m	100
Technetium-99	10
Tellurium-125m	10
Tellurium-127m	10
Tellurium-127	100
Tellurium-129m	10
Tellurium-129	100
Tellurium-131m	10
Tellurium-132	10
Terbium-160	10
Thallium-200	100
Thallium-201	100
Thallium-202	100
Thallium-204	10
**Thorium (natural)[1]	100
Thulium-170	10
Thulium-171	10
Tin-113	10
Tin-125	10
Tungsten-181	10
Tungsten-185	10
Tungsten-187	100
**Uranium (natural)[2]	100
Uranium-233	.01
Uranium-234- Uranium-235	.01
Vanadium-48	10
Xenon-131m	1,000
Xenon-133	100
Xenon-135	100
Ytterbium-175	100
Yttrium-90	10
Yttrium-91	10
Yttrium-92	100
Yttrium-93	100
Zinc-65	10
Zinc-69m	100
Zinc-69	1,000
Zirconium-93	10
Zirconium-95	10
Zirconium-97	10
Any alpha emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	.01
Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition	.1

35 FR 6425

Note.—For purposes of § 20.303, where there is involved a combination of isotopes in known amounts, the limit for the combination should be derived as follows. Determine, for each isotope in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific isotope when not in combination. The sum of such ratios for all the isotopes in the combination may not exceed "1" (i.e., "unity").

45 FR 71761

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[1] Based on alpha disintegration rate of Th-232, Th-230 and their daughter products.

[2] Based on alpha disintegration rate of U-238, U-234, and U-235.

* Amended 36 FR 16898.

** Amended 39 FR 23990.

49 FR 47823

APPENDIX D.—UNITED STATES NUCLEAR REGULATORY COMMISSION REGIONAL OFFICES

	Addresses	Telephone (24 hours)
Region I: Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont.	USNRC, 631 Park Avenue, King of Prussia, PA 19406.	(215) 337-5000 (FTS) 488-1000
Region II: Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, Puerto Rico, South Carolina, Tennessee, Virginia, Virgin Islands, and West Virginia.	USNRC, 101 Marietta Street, NW, Suite 2900, Atlanta, GA 30323.	(404) 221-4503 (FTS) 242-4503
Region III: Illinois, Indiana, Iowa, Michigan, Minnesota, Missouri, Ohio, and Wisconsin.	USNRC, 799 Roosevelt Road, Glen Ellyn, IL 60137.	(312) 790-5500 (FTS) 388-5500
Region IV: Arkansas, Colorado, Idaho, Kansas, Louisiana, Montana, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Texas, Utah, and Wyoming.	USNRC, 611 Ryan Plaza Drive, Suite 1000, Arlington, TX 76011.	(817) 860-8100 (FTS) 728-8100
Region IV: Field Office	USNRC, Region IV Uranium Recovery Field Office, 730 Simms Street, P.O. Box 25325, Denver, CO 80225.	(303) 234-7232 (FTS) 234-7232
Region V: Alaska, Arizona, California, Hawaii, Nevada, Oregon, Pacific Trust Territories, and Washington	USNRC, 1450 Maria Lane, Suite 210, Walnut Creek, CA 94596.	(415) 943-3700 (FTS) 463-3700

PART 20 STANDARDS FOR PROTECTION AGAINST RADIATION

PROPOSED RULE MAKING

45 FR 18023
Published 3/20/80
Comment period expires 3/8/80

10 CFR Part 20

Standards for Protection Against Radiation; Advance Notice of Proposed Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Advance Notice of Proposed Rulemaking; Request for Public Comment.

SUMMARY: The Nuclear Regulatory Commission. (NRC) is considering a major revision to 10 CFR Part 20 of its regulations. The primary purpose of the revision is to bring NRC radiation protection standards into accord with developments in radiation protection that have occurred since promulgation of Part 20 in its present form in the late 1950's. In a preliminary review of this matter, the NRC staff has identified a number of areas in which Part 20 might be improved. Before proceeding further with specific structural and substantive proposed changes, the NRC is seeking public comment. Of particular interest are public views on the areas so far identified by the staff as well as suggestions for further improvements and suggestions for alternative approaches for effecting needed improvements.

DATES: Comment period expires June 18, 1980.

ADDRESSES: Written comments or suggestions should be submitted to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch. Copies of comments received may be examined at the Commission's Public Document Room at 1717 H Street, N.W., Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Robert A. Purple, Assistant Director, Radiological Health & Safeguards Standards, Office of Standards Development, Nuclear Regulatory Commission, Washington, D.C. 20555 (Phone—(301) 443-5855).

SUPPLEMENTARY INFORMATION: The NRC radiation protection standards were developed in the late 1950's. Since that time there have been a substantial number of revisions, some of them to bring the regulation into accord with recommendations of various scientific advisory organizations, but none of them affecting the basic structure or fundamental approach to radiation protection embodied in the original publication. With the passage of time there has been an increase in the sophistication of the general approach to radiation protection, there have been several legislative actions that affect the federal approach to radiation protection, and there have been additional information and recommendations on radiation protection from national and international bodies (e.g., United Nations Scientific Committee on the Effects of Atomic Radiation, National Council on Radiation Protection and Measurements and the International Commission on Radiological Protection). In addition, there has been a growing public interest in and concern about the potential health effects of low-level ionizing radiation. In August 1979, the Secretary of Health, Education and Welfare sent to the President a report of an Interagency Task Force on the Health Effects of Ionizing Radiation. This report, among other things, made recommendations for reducing radiation exposures and recommended the establishment of a Federal Radiation Policy Council responsible for formulating broad radiation protection policy. The President has approved these recommendations. As part of its participation in this Task Force effort, the NRC recognized the desirability of reexamining the adequacy of its existing radiation protection standards.

For these reasons, the NRC is initiating a rulemaking proceeding for the purpose of modernizing its radiation protection standards. It is expected that this rulemaking proceeding will be complex and controversial. To provide for the earliest possible public participation in the development of proposed revisions, the NRC is seeking public comment and suggestions at this early stage in the process. In requesting public comments, the NRC recognizes that the EPA has responsibility for establishing Federal Radiation Guidance and generally applicable standards for the protection of the environment from radiation and radioactive materials, and is aware that EPA is actively developing new guidance and standards that would affect the provisions on NRC's radiation protection regulations which are derived from EPA guidance and standards. During the consideration of revisions to its radiation protection standards, NRC plans to work closely with the EPA to help ensure compatibility with forthcoming EPA guidance. One of the goals in revising the NRC radiation protection standards is to structure them in a way that will facilitate compliance with future radiation protection guidance issued by the EPA.

As a separate matter, the Commission is considering petitions that have recommended the lowering of numerical limits for individual doses. As part of the consideration of those petitions, it is anticipated that public hearings on the new EPA federal guidance for occupational exposures will be conducted jointly by EPA, NRC and OSHA in the near future (see 44 FR 53785, September 17, 1979) and numerical occupational dose limiting standards will be an issue covered at those hearings. If, as a result of the EPA guidance, revised numerical standards for NRC licensees are indicated, they will be promulgated.

In the above context, public comments on the absolute numerical limits that should be established in the radiation protection standards for nuclear workers and the public are not solicited as part of this notice. However, public comments are requested on the appropriateness of the specific items listed for individual doses and on the completeness of areas identified for further improvement by the NRC staff.

Function of Radiation Protection Standards

To aid in developing the framework on which to structure the new radiation protection regulations, it is helpful to have a general statement of the desirable characteristics of or objectives to be met by the new standards. To that end, the NRC staff has developed the following statement of purpose for NRC radiation protection standards:

Purpose: The NRC standards for protection against radiation should identify specific quantifiable and procedural requirements, and their bases, that will provide adequate

protection of the health and safety of workers, individual members of the public, and the population in general. NRC standards should be consistent with the applicable Federal radiation protection guidance and include consideration of the work of recognized National and International advisory organizations. The standards should be structured in a manner that is easily understood and can be readily revised to accommodate legislative and technical changes as necessary. To ensure compliance, implementation of the standards should be amenable to verification by the Commission's inspection programs. The regulation should be readily inspectable and enforceable so that timely and effective enforcement actions can be taken whenever the standards are violated.

The list of essential elements of the radiation protection standards which follows was developed with these objectives in mind.

Essential Elements of the Radiation Protection Standards

The NRC staff has tentatively identified what it considers to be the essential elements that should be contained in the NRC radiation protection regulations. The list of items follows:

a. Radiological Protection Principles.
These should include:
Identification of basic assumptions used for radiation protection purposes, such as: (1) there is within the range of exposure conditions usually encountered in radiation work, a linear relationship without threshold between dose and probability of stochastic effect; and (2) the severity of each type of stochastic effect is independent of dose.
Identifications of the basic radiation protection principles which are derived from the assumptions, such as:
(1) No practice or operation involving exposures to radiation should be adopted unless its introduction produces a positive net benefit;
(2) All exposures shall be kept as low as reasonable achievable, economic and social factors being taken into account, and
(3) The dose equivalent to individuals shall not exceed the limits selected for the appropriate circumstances.
(4) Persons occupationally exposed to radiation should be informed of the potential risk of that exposure.

b. Standards for Individual Occupational Exposures.
These should include:
(1) Numerical dose limits (internal, external, and in combination) for specific time periods.
(2) Consideration of special provisions for limiting exposures of susceptible groups (e.g., embryo/fetus, women in general, fertile women and minors), applicable laws being taken into account.
(3) Controls for transient workers, contract workers, and "moonlighters".
(4) Derived standards, e.g., maximum permissible concentration (MPC), surfact contamination in restricted areas, annual limits of intakes (ALI).
(5) Provisions for planned special exposures and overexposure situations.
(6) Provisions for emergency exposures.

c. Standards for Exposures of the General Public
These should include:
(1) Numerical dose limits (internal, external, and in combination) for specific time periods including consideration of special population groups.
(2) Effluent release limits including ALARA (as low as reasonably achievable) numerical guides and consideration of special population groups.
(3) Derived standards, taking into account major exposure modes and pathways, e.g., MPC air, MPC water, milk chain, ALI, etc.
(4) Siting considerations, including special population groups for licensed facilities and activities other than LWR power stations.
(5) Emergency dose limits reflecting Federal guidelines.
(6) Limits of contamination for the release of material for unrestricted use.
(7) Limits for burial of radioactive waste in other than licensed burial grounds (i.e., 10 CFR Part 20, 20.304).
(8) Limits of contamination, in terms of concentration and total activity, for disposal of material as non-radioactive waste.

d. Requirements for a Radiation Protection Program
These should include:
(1) Training requirements
(2) Management audits and controls
(3) Designation and marking of radiation areas
(4) ALARA program requirements including guidance on lifetime accumulative doses
(5) Access controls, including alarms
(6) Personnel dosimetry requirements, (for both internal and external exposures) including performance standards for health physics measurements
(7) On-site radiation and contamination measurements (instruments, performance standards, etc.)
(8) Environmental radiation monitoring (off-site)
(9) Procedures for transportation of radioactive material
(10) Procedures for responding to emergency situations
(11) Procedures for radiation protection
(12) Procedures for managing overexposures
(13) Procedures for radioactive waste disposal.

e. Record Keeping Requirements
These should include:
(1) Individual doses (internal and external) and bases for estimates
(2) Identity and quantity of radioactive materials released to the environment
(3) Survey and monitoring results
(4) Disposal of licensed material
(5) Receipt, transfer, and inventory of radioactive material

f. Reporting Requirements
These should include:
(1) Routine reports of occupational doses (including both internal and external exposures)
(2) Overexposure reports
(3) Reports of effluents released to the environment
(4) Reports of theft or loss of radioactive material
(5) Notification of incidents.

Areas In Part 20 That Need Improvement

Based partly on the NRC staff's views on the necessary elements of a revised Part 20 as presented above, and also on a critical examination of the present Part 20, the following list of areas where Part 20 could be improved has been identified. It would be the intent of the staff to ensure that these areas are resolved in a proposed revision to Part 20.

a. Radiological Protection Principles
(1) The underlying radiation protection principles adopted by NRC should be presented in terms understandable to laymen.
(2) The ALARA principle and requirements for both effluents and occupational exposures should be strengthened. Quantitative occupational ALARA guidelines should be established wherever possible for NRC licensed facilities. Collective doses should be addressed.

b. Standards for Individual Occupational Exposure
(1) Consideration should be given to adopting the ICRP recommendations on the use of "effective dose equivalents" and dose limitations for combined internal and external exposures. Present part 20 does not preclude radiation exposure as high as a total of 17 rem of combined internal and external dose to the whole body in a single year, i.e., 5 rem internal plus (3 rem per qtr. × 4 qtr. =) 12 rem external doses.

(2) Derived limits for concentrations in air and water should be "updated" or replaced by annual limits for intake.

(3) Standards applicable to emergency or overexposure situations should be presented.

(4) Special provisions to limit collective doses should be considered.

(5) Special provisions for limiting exposures of susceptible groups (e.g. embryo/fetus, women in general, fertile women and minors) should be considered, under applicable law.

(6) Controls for "moonlighters", contract workers, and transient workers should be strengthened.

c. Standards for Exposure of the General Public

(1) Additional consideration should be given to exposure pathways to man other than by air and water intake.

(2) Derived limits for concentrations in air and water should be "updated" or replaced by annual limits for intake.

(3) Special provisions for limiting exposures of susceptible groups (e.g. embryo/fetus, women in general, fertile women and minors) should be considered, under applicable laws.

(4) Standards for licensee action applicable to emergency or overexposure situations should be presented.

(5) Standards for environmental monitoring for either routine or accident conditions should be presented.

d. Requirements for a Radiation Protection Program

(1) The basic elements of an acceptable radiation protection program should be presented.

e. Reporting Requirements

(1) Reporting of routine internal exposures should be required.

(2) Reporting of the rupture or failure of sealed radiation sources.

f. Miscellaneous

(1) The adoption of SI (Systeme Internationale) units with related conversion formulas should be considered (for example, radiation doses in units of grays and sieverts and activity in units of becquerels).

(2) Performance standards (accuracy and reliability) for health physics measurements should be presented.

(3) The technical bases for numerical limits should be readily identifiable.

It must be emphasized that the items listed above do not represent decisions or commitments. Rather, as stated previously, they are the result of a preliminary review by the NRC staff and are published at this time to solicit views of interested persons not only on the appropriateness of the specific items listed but also to facilitate identification of further improvements or revisions to Part 20 not yet identified by the staff.

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45 FR 20493
Published 3/28/80
Comment period expires 5/27/80
extended to 6/27/80

10 CFR Part 20

Advance Notice of Rulemaking on Certification of Personnel Dosimetry Processors

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Advance notice of rulemaking to improve accuracy in personnel dosimetry.

SUMMARY: Tests have indicated that a significant percentage of personnel dosimetry processors may not be performing with an appropriate degree of accuracy. Alternatives for action to correct this situation are presented. Interested persons are invited to submit comments on these alternatives.

DATES: Comment should be received by May 27, 1980.

ADDRESSES: Comments or suggestions for consideration in connection with these alternatives may be sent to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch. Copies of comments received may be examined at the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Mr. Robert E. Alexander, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, 301-443-5975.

SUPPLEMENTARY INFORMATION: Recent tests indicate that a significant percentage of the personnel dosimetry processors in the United States are not performing with a degree of accuracy acceptable to the NRC when compared against a consensus standard prepared under the auspices of the American National Standards Institute.[*] To the extent that these test results are representative of routine field conditions, the results indicate that the dose received by occupationally exposed personnel may often be considerably different from the dose reported by the dosimetry processor. Where complete reliance for individual dose determinations is placed on personnel dosimeters, control of individual radiation exposures may not be accomplished as well as is indicated, and compliance with regulatory dose limits may not, in fact, be achieved. The test results indicate that individual doses may be over or understated. Further, these incorrect measurements could become a source of error when the dosimetry data are used in epidemiological studies intended to investigate the does-effect relationship.

The principal causes of the inconsistent test measurements that have been observed are not well understood. There is some evidence that the inconsistencies are due primarily to differences between the dosimeter irradiation techniques used by the tester and the calibration methods used by the processors; this possiblility is discussed in the following paragraph. However, actual inaccuracies may arise because of inadequate quality control in dosimeter manufacturing or in a few cases because of ineptitude on the part of the processor. These different problems would require different solutions, so that appropriate regulatory corrective action is very dependent on a better understanding of the causes of the problem.

Regarding the adoption of methods for correcting this problem, it is evident from at least two important considerations that caution should be exercised. First, as previoulsy mentioned, the inconsistent test measurements refer to differences between the amount of radiation delivered to a dosimeter, under highly controlled laboratory conditions, by the individuals conducting the test, and the amount of radiation subsequently reported by the processor. These tests do not necessarily measure the difference between the radiation delivered to a dosimeter worn by a worker and the radiation subsequently reported by the processor. For example, the radiation source used by the processor to calibrate the dosimeter may emit radition of the same or very similar quality as the radiation to which the worker is exposed, but may be quite different from the radiation used by the tester to irradiate the processor's test dosimeters. Thus, standardization of calibration techniques among U.S. processors, which may be essential for achieving good performance in a test program, could in some cases produce apparent improved accuracy while actually introducing greater errors in the personnel dose measurement process.[**] This consideration is an integral part of the personnel dosimetry problem and must receive full consideration in corrective action planning.

Secondly, any regulatory action taken must be handled in a manner to ensure that sufficient personnel dosimetry services remain available. Unnecessarily severe or improper corrective action could reduce the number of available processors to the extent that the dose determinations for some workers could be adversely affected.

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[*] Pilot study conducted for the NRC by the University of Michigan.

[**] For example, a processer may calibrate beta dosimeters for workers at a uranium fuel fabrication plant using a uranium slab; the tester may use a strontium-90 source. The processor could then measure the workers' doses accurately but could fail the performance test.

One of the major sources of error in personnel dosimetry is known to be the potential difference between the actual dose received by the dosimeter and the actual dose received by the wearer. Such differences can, for example, be due to shielding of the dosimeter by the body when the worker is not facing the source of radiation or due to different irradiation of the part of the body on which the dosimeter is worn than of other parts of the body. These sources of error are recognized but are not part of the dosimeter processing problem that is being considered for correction.

A Federal Interagency Policy Committee on Personnel Dosimetry Performance has been formed to guide and coordinate correction of the dosimetry processor performance problem. Represented on this Committee are: the Bureau of Radiological Health (HEW), the Department of Defense, the Department of Energy, the Environmental Protection Agency, the National Bureau of Standards (NBS), the Nuclear Regulatory Commission, the Occupational Safety and Health Administration (DOL), and the Conference of Radiation Control Program Directors (States). Dosimetry processors and users have indicated agreement that some corrective action is appropriate. A working group of the Health Physics Society Standards Committee (HPSSC) has developed and the American National Standards Institute (ANSI) has published a draft standard for dosimetry performance (N13.11, July 1978). This standard is considered to be the most important element in a corrective program. An industry committee (Personnel Dosimetry Overview Committee) has been formed to assist in ensuring that any proposed regulatory action is effective and appropriate to the need. However, agreement has not been reached as to the specific action that should be taken. Alternative corrective actions under consideration are discussed below.

Recent Federal Government Action

Some time ago, on November 30 and December 1, 1976, the Nuclear Regulatory Commission and other Federal agencies conducted a public meeting at which the personnel dosimetry performance problem was discussed in an open forum by personnel dosimetry processors, dosimetry users, and representatives of State governments and Federal agencies. Other co-sponsors of this meeting were the Energy Research and Development Administration (now the Department of Energy) and the Bureau of Radiological Health. These discussions revealed general agreement that a personnel dosimetry problem does exist and that the problem is sufficiently broad in scope that it should be addressed by the Federal government. However, many of the attendees cautioned against precipitous action and strongly recommended a pilot study (1) to evaluate the draft HPSSC/ANSI standard and (2) to provide precessors the opportunity to take any necessary corrective actions in their operations prior to the implementation of new Federal regulations on the dosimetry performance problem. These recommendations were accepted, and the Nuclear Regulatory Commission (NRC) subsequently issued a contract to the University of Michigan (UM) to conduct a two-year pilot study. The objectives of this study were:

(1) To determine whether the draft HPSSC/ANSI standard provides an adequate and practical test of dosimetry performance;

(2) To give processors an opportunity to correct any problems that are uncovered;

(3) To develop operational and administrative procedures to be used later by a permanent testing laboratory.

The study was completed December 31, 1979.

Conditions of the contract included a provision that any personnel dosimetry processor in the United States would be allowed to participate in the study on a strictly voluntary basis, provided only that the dosimeters tested be restricted to those used to provide the permanent record of occupational exposures. Processors were told that the UM would keep test results confidential (i.e., that no organization other than the UM would be able to associate specific results with the name of a processor), that all results would be published (in coded form), that the UM would charge no fee for participation, that the new HPSSC/ANSI standard would be used to evaluate their performance, that each participant would be given the opportunity to be tested twice and would also be given an opportunity to discuss with UM personnel the possible reasons for any poor performance prior to the second round of tests, and that the accuracy of the irradiations provided by the UM would be verified by the NBS, and that UM facilities and equipment would be open to inspection by the participants prior to the beginning of the tests. An open house was conducted for the latter purpose by the UM on April 20, 1978. Fifty-nine processors participated in the study; it is believed that very few U.S. processors did not participate. During the course of this study, the UM submitted monthly progress reports to the NRC. These reports are available for inspection or copying in the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C. Copies may also be obtained by contacting the Public Document Room, (202) 634-3273. The final report for the study, NUREG/CR-1064, may be purchased from National Technical Information Service, Springfield, Virginia 22161.

The draft standard allowed processors to be tested in eight different radiation categories. The term "category" refers to the type of radiation being measured. For example, Category 1 is gamma radiation, Category 2 is high energy X-radiation, Category 3 is low energy X-radiation, etc. Within each category of the draft standard were several dose ranges called intervals. The consensus standard used in the pilot study evaluated a processor's ability to consistently and accurately perform within a specific tolerance limit for each interval. Failure to pass one interval within the category would cause a processor to fail the entire category test. A performance index, P, was calculated for each dosimeter as (reported dose minus the delivered dose) divided by the delivered dose. For each interval, the average performance index, P, and its standard deviation, S, were calculated. The draft standard incorporated a statistical test, $|\bar{P}| + 2S$ equal to or less than a specific tolerance value. The tolerance value for any given interval was a function of the average delivered dose and varied from 0.3 to 2.0. A processor could only pass a given category if all intervals of a respective category were passed.

At the conclusion of the first round of testing, the results were examined by the NRC staff, by the Interagency Policy Committee on Personnel Dosimetry Performance, and by the industry's Personnel Dosimetry Overview Committee. The results indicated poor performance on the part of many processors. Only 23% of the category tests attempted by the processors were passed, using the criteria in the HPSSC/ANSI standard. None of the processors passed all of the tests attempted in the first round, but every category test was passed by at least one processor. These facts indicate that the standard is achievable and suggest that the problem may lie with the processor and/or with differences in irradiation techniques used by the UM and those used by the processors during their calibration procedures. The participants' performance in the first round was also evaluated used a simple percentage-passed basis (as opposed to the more complicated statistical formula of the standard). Again, generally poor performance was indicated. Using a simple ±30% pass-fail criterion for each and every dosimeter in a category during the first round of tests, the weighted average of all the processors reveals 7% of the category tests were passed (i.e., all dosimeters tested in all intervals of the category fell within the ±30% criterion). Using a ±50% criterion in the same manner, 21% of the category tests were passed. Thus, the results using the draft standard are similar to those using the ±50% criterion.

It had been anticipated at the beginning of the pilot study that processors who performed poorly during the first round of testing would be able to take corrective action prior to the second round and would improve their performance. The second-round results did indicate improvement over the first round. Approximately 35% of the category tests were passed. Using a simple ±30% pass-fail criterion for each dosimeter in a category during the second round of tests, the weighted average of all the processors reveals 19% of the category tests were passed (i.e., all dosimeters tested in all intervals of the category fell within ±30% criterion). Using a ±50% criterion in the same manner, 32% of the category tests were passed.

Processor performance was not based on the percentage of dosimeters that individually passed the criteria set forth in the standard. Of the 23,000 individual dosimeters evaluated during the pilot study, 85% of the dosimeters tested passed round one of the tests and 90% of the dosimeters passed in the second round. Failure of the 15% and 10% of the dosimeters tested, to meet minimum tolerances established by the HPSSC/ANSI in the standard is an unsatisfactory level of performance when determining individual dose assessments. In the pilot study, for example, high doses (i.e., 600 rads) delivered to some of the test dosimeters were actually undetected by some of the processors.

One processor, whose results in the first round were very poor, worked with UM personnel to identify and effect the necessary changes in the process and then performed very well during the second round, passing all categories attempted but one. Another processor passed all eight of the categories. These facts provide rather strong indications that conformance with the standard is attainable, but that many processors have not made the necessary changes in their operations.

After considering this situation, the Interagency Committee on Personnel Dosimetry Performance made the following recommendations:

(1) The actual causes of the poor performance should be determined with a greater degree of certainty before finalizing plans for corrective action;

(2) A notice should be published in the **Federal Register** for the purpose of notifying all personnel dosimetry processors and the public that the Federal Government is determined to take action as necessary to correct the personnel dosimetry problem.

Subsequently, the NRC staff authorized the UM to conduct a series of site visits with eight of the largest processors to try to determine the causes of poor performance. At the conclusion of these site visits, the UM personnel prepared a report which indicates four major causes:

(1) Inadequate calibration sources.

(2) Variability in the thermoluminescent dosimeter chips.

(3) Clerical errors.

(4) Lack of effort on the part of the processors to make the changes necessary to pass the tests.

This report, dated May 1979, is available in the Commission's Public Document Room in the file on personnel dosimetry performance testing.

Future Action

The pilot study was completed by the UM on December 31, 1979. Future action will be based in part on the final report. However, it is possible at this time to identify the following actions that the NRC has under consideration.

Processor Certification

According to this plan, the NRC would issue new regulations stating that personnel dosimetry results would be acceptable only if provided by a processor who is certified by a testing (i.e., certifying) laboratory approved by, or specified by, the NRC.

These processors would have to obtain and maintain their certification by passing, at a specified frequency, performance tests conducted by the certifying laboratory. The certifying laboratory(s) would use performance criteria published by the American National Standards Institute (ANSI) and referenced in the new regulations. These regulations: (1) Would adopt, possibly in modified form, the final ANSI standard evolving from draft ANSI standard N13.11; (2) would specify how frequently processors would have to demonstrate, through testing, their ability to comply with this standard; (3) would establish the procedure to be used by the NRC to let its licensees know which processors have been certified as well as those who have lost their certification; (4) would (except for one possibility noted below) name the testing and certification laboratory(s) required to be used; (5) would stipulate that the laboratory(s) would be monitored for technical competence by the National Bureau of Standards; and (6) would specify the procedure to be used for reinstating processors who have lost their certifications and have appealed.

Subsequently, other affected Federal and State agencies would be likely to consider adopting similar regulations. Although it is estimated that only about 15% of U.S. personnel occupationally exposed to measurable ionizing radiation (e.g., above 30 mrems per month) are engaged in NRC-licensed activities, it should be recognized that any NRC regulations in this area would affect a much larger percentage. This is true because most commercial processors serve customers other than NRC licensees, and any improvements in their operations would be likely to benefit all of their customers rather than just the NRC licensees.

Several alternatives are possible as to the operation of the testing and certification laboratory(s):

(1) *Unspecified Laboratory(s).* This alternative would require an amendment to the NRC regulations as described above but without naming the testing laboratory(s). The processors and users would thereby be left to their own initiatives to establish one or more laboratories, which would have to be monitored by the NBS. The NRC would have no control over the laboratory(s), except through regulations applying to its licensees. However, if it is stipulated that the licensee must obtain personnel dosimetry results under conditions as described above (except for naming the testing and certification laboratory(s)), NRC licensees could only use a processor who complies with these conditions, including monitoring by the NBS.

(2) *NRC-Operated Laboratory.* This alternative would also require an amendment to the NRC regulations as described above, but the testing laboratory would be a Government facility managed and operated by NRC employees. By charging an appropriate testing fee, costs for establishing, maintaining, and operating the laboratory could be recovered.

(3) *NRC-Contracted Laboratory.* Similar regulation amendments would be needed for this alternative, but the laboratory would be operated by an NRC contractor, using the contractor's facilities. Funding would be provided by testing fees.

(4) *Federal Government (non-NRC) Operated Laboratory.* Similar regulation amendments would be needed for this alternative, but this testing laboratory would be operated by an agency of the Federal Government other than the NRC, preferably by one of the agencies experienced in laboratory testing work. Existing expertise could be utilized, or qualified personnel could be employed. The facilities would be Government-owned; funding would be provided by testing fees.

Invitation To Comment

Information pertaining to the personnel dosimetry problem discussed in this notice is invited, including comments on the alternative solutions described, suggestions of other alternatives, and estimates of costs anticipated in the process modifications necessary to permit successful passing of the ANSI standard criteria. Comments should be received by May 27, 1980.

45 FR 31118
Published 5/12/80
Comment period extended to 6/27/80.

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10 CFR Part 20

Extension of Comment Period on Advance Notice of Rulemaking on Certification of Personnel Dosimetry Processors and Public Meeting

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Announcement of a public meeting on personnel dosimetry performance testing and extension of the written comment period with respect to an advance notice of rulemaking on certification of personnel dosimetry processors.

SUMMARY: The Nuclear Regulatory Commission (NRC) recently published an Advance Notice of Rulemaking on Certification of Personnel Dosimetry Processors (45 FR 20493, March 28, 1980). The NRC will hold a public meeting to discuss with processors and others methods of improving the consistency and accuracy of dosimetry results, to review the Advance Notice of Rulemaking and the regulatory alternatives identified therein, to discuss elements of quality assurance programs, and to obtain oral comments. The comment period on the Advance Notice, which was to have closed May 27, is being extended to June 27, 1980.

DATES: (1) New comment period expires June 27, 1980.

(2) Meetings will be held May 28 and 29, 1980, from 8:30 a.m. to 4:30 p.m. Inquiries and requests to make prepared presentations should be directed in writing or telephoned no later than May 23, 1980 to Nancy A. Dennis at the address below.

ADDRESSES: (1) Comments or suggestions for consideration in connection with these alternatives should be submitted to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention Docketing and Service Branch. Copies of comments received may be examined at the NRC Public Document Room, 1717 H Street, NW, Washington, D.C.

(2) The meetings will be held in the auditorium of the General Services Administration Building, 18th and F Streets, NW., Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Nancy A. Dennis, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, (301) 443-5970.

SUPPLEMENTARY INFORMATION: An Advance Notice of Rulemaking on Certification of Personnel Dosimetry Processors appeared in the Federal Register March 28, 1980, on which the comment period was to close May 27, 1980. The comment period is hereby extended 30 additional days, to June 27, 1980, to allow attendees to the Public Meeting also being announced by this Notice time to supplement or revise their comments on the Advance Notice. The Commission staff believes that it would be helpful in this rulemaking process (1) to provide an opportunity in an open forum for discussion of reasons for poor performance by some dosimetry processors in a pilot study recently conducted for the NRC by the University of Michigan, and for pilot study participants to discuss with each other and the NRC staff any experiences during the pilot study which led to process improvements or which for any other reason should be taken into consideration by the staff (this meeting and the Advance Notice should provide processors with the opportunity to discuss and to effect necessary process changes well before the new regulations go into effect), (2) to review the Advance Notice of Rulemaking and the regulatory alternatives identified therein, (3) to discuss the elements of dosimetry quality assurance programs, and (4) to obtain oral comments. Oral presentations on the above subjects will be made by NRC staff personnel and by Dr. Phillip Plato, University of Michigan, contractor to the NRC. Participants who indicate in advance their desire to make prepared presentations will be allowed to do so. Advance notice of intent to make prepared presentations must be received by May 23, 1980; notice by telephone is acceptable. Time permitted for these presentations will be limited to 10 minutes each. Written comments of any length will be accepted at the meeting or may be submitted to the address indicated in the Advance Notice. Additional information on this subject is provided in the following three documents which discuss and report the results of the pilot study: NUREG/CR-1063 (Procedures Manual), NUREG/CR-1064 (Final Report), and NUREG/CR-1304 (Supplementary Report). Copies may be obtained from GPO Sales Program, Division of Technical Information and Document Control, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, or from the National Technical Information Service, Springfield, Virginia 22161. Copies of the meeting transcript and written comments submitted may be obtained from the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C. 20555.

48 FR 20721
Published 5/9/83
Comments should be submitted on or before 6/23/83. Comments received after this date will be considered if it is practicable to do so, but assurance of consideration cannot be given except as to comments received on or before that date.

10 CFR Part 20

Reports of Theft or Loss of Licensed Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission is considering amending its regulations concerned with reports of theft or loss of licensed material. The proposed amendment would modify that part of the regulation which permits licensee judgment in the reporting of loss or theft of licensed material, with a requirement that the licensee report all licensed material (in a quantity greater than the minumum specified in the amended regulation) lost, stolen or missing for more than 30 days after its absence becomes known to the licensee. Modification of this judgmental condition will result in the reporting of all significant losses or thefts and will provide assurance that adequate radiological safety evaluation, for the purpose of protecting the public, are made by the NRC as well as the licensee in investigating the circumstances surrounding any loss or theft of licensed material.

DATES: Comments should be submitted on or before June 23, 1983. Comments received after this date will be considered if it is practicable to do so, but assurance of consideration cannot be given except as to comments received on or before that date.

ADDRESSES: Submit written comments on the proposal and/or the supporting value/impact statement to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch. Single copies of the value/impact statement may be obtained on request from the contact identified below. Copies of the value/impact statement and of comments received by the Commission may be examined in the Commission's Public Document Room at 1717 H Street NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Donald O. Nellis, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 443–5825.

SUPPLEMENTARY INFORMATION:

Background

On November 12, 1980, the Radiation Safety Officer on an NRC licensee notified the Nuclear Regulatory Commision of the loss or theft of a package of licensed material. The package, containing 10 12.5-millicurie cesium-137 sealed sources, was placed in the transportation system to be shipped to South Korea in February 1979. In September 1979, the licensee was notified that the package had not been received. It did not, however, report the loss or theft to the Nuclear Regulatory Commission, in accordance with 10 CFR 20.402, until November 1980 because it believed that the unopened package was somewhere within the transportation sytem and did not constitute a significant hazard to person in unrestricted areas.

The Cs-137 sources were contained in a sealed lead-pipe shield, held in a plywood frame in the center of a Department of Transportation Specification 7A package. Radiation levels from the package were reported to be 1.8 mR/hr (millirem/hour) at 3 feet and 16 mR/hr on contact.

Assuming that the package had indeed been opened, radiation levels of 48 mR/hr at 3 feet, 436 mR/hr at 1 foot, and 1742 mR/hr at 6 inches would have been present. These radiation levels are considerably in excess of the level specified for unrestricted areas in § 20.105.

The Nuclear Regulatory Commission considers that inexcusable delays in reporting missing material such as described above, could, under plausible circumstances, constitute significant hazards to persons engaged in the transportation industry and to the public in general. The staff recognizes that currently 10 CFR 20.402 due to its judgmental language does not require a report if a licensee believes that a loss or theft does not constitute a substantial hazard in unrestricted areas. A Notice of Violation was issued to the licensee in this case because of its failure to exercise reasonable judgment. However, the NRC staff thinks that the existing regulations should be amended to require licensees to apply a common standard to the reporting of lost or stolen licensed material. This approach is in keeping with a recent Commission policy statement concerning the responsibility of licensees, published in the Federal Register of July 20, 1982 (47 FR 31482). The Commission, therefore, is proposing to amend § 20.402 to modify the judgmental language which allows the licensee to decide whether or not to report a loss or theft of licensed material. In order to reduce the number of reports required under the amended version of § 20.402, the Commission has decided that only losses or thefts of licensed material in quantities greater than 10 times the quantities specified in Appendix C of Part 20 need be reported. The bases for this judgment are § 20.303(b)(2) which permits licensees to discharge into sanitary sewage systems 10 times the quantities specified in Appendix C of Part 20, and § 32.19(a) which permits the sale or transfer of up to 10 exempt quantities (as set forth in § 30.71, Schedule B) in a single transaction.

Proposed Action

The NRC is proposing to amend § 20.402 to modify the judgmental part of the present regulations so that all licensed material (in a quantity greater than the minimum specified in the amended regulation) missing for more than 30 days will be reported without regard to the hazard involved to persons in unrestricted areas.

Paperwork Reduction Act Statement

In NRC regulations, there are a number of requirements for the reporting of situations where specified materials are lost, stolen or missing. These requirements already achieve the goals of the proposed § 20.402 for these materials and situations. Accordingly, the proposed amendment provides that a licensee who files a report of material lost, stolen or missing under one of these requirements need not file a report under the proposed amendment. A list of the pertinent regulations is found in paragraph (d) of the amended regulatory text.

The proposed rule will be submitted to the Office of Management and Budget for clearance of the reporting requirements that may be appropriate under the Paperwork Reduction Act [Pub. L. 96–511]. The SF–83 "Request for Clearance," Supporting Statement, and related documentation submitted to OMB will be placed in the NRC Public Document Room at 1717 H Street NW., Washington, D.C. 20555. The material will be available for inspection and copying for a fee.

Regulatory Flexibility Certification

On the basis of information available to it, the NRC, in accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), hereby certifies that this rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.

There are approximately 8,000 NRC fuel cycle and materials licensees of which approximately one half or 4,000 qualify as small entities and consist for the most part of hospitals or medical facilities. The present reporting requirements under § 20.402 result in approximately 25 reports annually (from all 8,000 licensees) which require licensees to devote an average of 3 hours for each report or a total of 75 staff hours annually. The proposed amendment could result in 30 to 35 additional reports annually for a total increase of roughly 100 licensee staff hours spread out among the 8,000 licensees. The Commission will welcome any comments regarding this Regulatory Flexibility Certification.

List of Subjects in 10 CFR Part 20

Byproduct material, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Penalty, Radiation protection, Reporting requirements, Special nuclear material, Source material, Waste treatment and disposal.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, notice is hereby given that the NRC is proposing to adopt the following amendments to 10 CFR Part 20.

PART 20—STANDARDS FOR PROTECTION AGAINST RADIATION

1. The authority citation for Part 20 is revised to read as follows: Authority: Secs. 53, 63, 65, 81, 103, 104, 161, 68 Stat. 930, 933, 935, 936, 937, 948, as amended (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273), §§ 20.101, 20.102, 20.103(a), (b), and (f), 20.104(a) and (b), 20.105(b), 20.106(a), 20.201, 20.202(a), 20.205, 20.207, 20.301, 20.303, 20.304 and 29.305 are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§ 20.102, 20.103(e), 20.401–20.407, 20.408(b), and 20.409 are issued under sec 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

2. Section 20.402 is amended as follows:

a. Paragraphs (a) and (b) are revised.

b. New paragraphs (c) and (d) are added.

c. Existing paragraphs (c) and (d) are redesignated (e) and (f), respectively.

§ 20.402 Reports of theft or loss of licensed material.

(a) Each licensee shall report by telephone to the Regional Administrator of the appropriate Nuclear Regulatory Commission Regional Administrator of the appropriate Nuclear Regulatory Commission Regional Office listed in Appendix D of this part:

(1) Immediately after its occurrence becomes known to the licensee, any lost, stolen or missing licensed material in such quantities and under such circumstances that it appears to the licensee that a substantial hazard may result to persons in unrestricted areas; or

(2) Within 30 days after the occurrence of any lost, stolen or missing licensed material becomes known to the licensee, all licensed material (in a quantity greater than 10 times the quantity specified in Appendix C of this part) which is still missing at this time unless the material has already been reported under paragraph (a) (1) of the section.

(b) Each licensee who is required to make a report pursuant to paragraph (a) of this section shall, within 30 days after making the telephone report required under paragraph (a), make a report in writing to the appropriate NRC Regional Office listed in Appendix D with copies to the Director of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, setting forth the following information:

* * * * *

(c) Lost or missing licensed material, for the purpose of this section, means any licensed material whose location is unaccounted for. It includes such material which has been shipped but has not reached its destination and whose location cannot be readily traced in the transportation system.

(d) A duplicate report is not required if the licensee is required to submit a report pursuant to §§ 30.55(c), 40.64(c), 50.72, 70.52, 73.27(b), 73.67(e)(3)(vi), 73.67(g)(3)(iii), 73.71 or 150.19(c) of this chapter.

* * * * *

Dated at Bethesda, Maryland this 14th day of February 1983.

For the Nuclear Regulatory Commission.

William J. Dircks,

Executive Director for Operations

49 FR 1205
Published 1/10/84
Comments must be received on or before 3/12/84. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

10 CFR Part 20

Improved Personnel Dosimetry Processing

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: Tests have indicated that a significant percentage of personnel dosimetry processors may not be performing with a reasonable degree of accuracy. Current regulations do not address the competency of these processors. The Nuclear Regulatory Commission (NRC) is proposing amendments that would require its licensees to utilize the specified services of processors that have been accredited by the National Voluntary Laboratory Accreditation Program of the National Bureau of Standards.

DATES: Comments must be received on or before March 12, 1984. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

ADDRESSES: Interested persons are invited to submit written comments and suggestions on the proposed rule, the supporting Regulatory Analysis and the Initial Regulatory Flexibility Analysis to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch. Comments may also be delivered to Room 1121, 1717 H Street NW., Washington, DC, between 8:15 a.m. and 5:00 p.m. Copies of the Regulatory Analysis, the Initial Regulatory Flexibility Analysis, and of comments received by the Commission regarding this rulemaking may be examined in the Commission's Public Document Room at 1717 H Street NW., Washington, DC. Single copies of the Regulatory Analysis and Initial Regulatory Flexibility Analysis may be obtained on request from Margaret V. Federline, Occupational Radiation Protection Branch, Division of Facility Operations, Office of Nuclear Regulatory Research, Mail Stop NL 5650, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

FOR FURTHER INFORMATION CONTACT: Margaret V. Federline, Division of Facility Operations, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Mail Stop NL 5650, Washington, DC 20555, telephone (301) 443–7686; inquiries regarding the Laboratory Accreditation Program for Personnel Dosimetry Processors at the National Bureau of Standards should be addressed to Robert L. Gladhill, Office of Laboratory Accreditation, National Voluntary Laboratory Accreditation Program, National Bureau of Standards, Technology B–141, Washington, DC 20234, telephone (301) 921–3431.

SUPPLEMENTARY INFORMATION:

Personnel dosimeters are devices worn by workers to monitor their exposure to radiation. NRC licensees are required to perform personnel monitoring as specified in 10 CFR Part 20, § 20.202, and to record and maintain radiation exposure records as specified in § 20.401.

Several types of personnel monitoring devices are available:

1. Whole body or whole body and skin personnel dosimeters, such as film badges including track-etch type dosimeters, and thermoluminescent dosimeters (TLDs) including albedo dosimeters;
2. Extremity dosimeters for assessing dose equivalent to hand and forearms, feet and ankles; and
3. Pocket ionization chambers, including direct-reading and indirect-reading dosimeters.

After being exposed to radiation, personnel dosimeters (with the exception of pocket ionization chambers) must be processed to estimate the radiation dose received by the individual while wearing the device. Dosimeters are collected from workers at various prescribed time intervals and processed either by the licensee in-house or by a commercial dosimetry processor(s). Personnel dosimeters appear to be capable of providing consistently accurate information on the amount of radiation received, provided the dose recorded by the dosimeter is above the detection threshold, e.g., about 20 mrems for photons. However, personnel dosimeters must be processed accurately and consistently, and interpreted correctly to provide adequate dose estimates. Data from the processing of personnel dosimeters are the basis for licensee and NRC records of external doses to workers.

Several dosimetry processor performance studies conducted between 1967 and 1976 indicated poor performance (excessive bias and variance) of processor's dosimeters when tested against a number of early performance standards; [1] these studies clearly demonstrated the need for common performance criteria for both film and thermoluminescent dosimeter (TLD) processor testing. As a result of these studies and strong encouragement by the Task Force on Personnel Dosimetry of the Conference of Radiation Control Program Directors (which represents the States), the NRC, the Bureau of Radiological Health (now the National Center for Devices and Radiological Health), and the Energy Research and Development Administration (now the Department of Energy) jointly conducted a public meeting in 1976 at which the personnel dosimetry performance problem was discussed in an open forum by personnel dosimetry processors, dosimetry users, and representatives of State Governments and Federal agencies. These discussions revealed general agreement that a personnel dosimetry problem does exist and that the problem is sufficiently broad in scope that it should be adddressed by the Federal government, since voluntary standards programs for personnel dosimetry processors have historically failed to achieve wide participation and acceptance from the personnel dosimetry processing industry. Also, copies of a draft performance standard, which designed to establish uniform criteria for testing the performance of film and TLD dosimetry processors, were distributed at the meeting. The draft standard was written by a working group of the Health Physics Society Standards Committee (HPSSC) and was subsequently published in draft form by the American National Standards Institute (ANSI) as ANSI Standard N13.11.

Many of the 1976 public meeting attendees cautioned against precipitious action by any Government agency and strongly recommended a pilot study (1) to evaluate the newly formulated draft HPSSC/ANSI Standard N13.11, and (2) to provide processors the opportunity to take any necessary corrective actions in their operations prior to the implementation of new Federal regulations on the dosimetry performance problem.

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[1] C. M. Unruh, et al., "The Establishment of and Utilization of Film Dosimeter Performance Criteria." BNWL–542, (1967). Battelle Northwest Laboratories, Richland, Washington.

L. Nichols and C. Newton, Jr., "Performance Tests of Commercial Personnel Monitoring Services." July 25, 1974–January 25, 1975, Battelle Northwest Laboratory, Richland, Washington. Unpublished Report—Available NRC Public Document Room, 1717 H Street NW., Washington, DC 20555.

L. L. Nichols, "A Test of the Performance of Personnel Dosimeters," BNWL–2159 (1977), Battelle Northwest Laboratory, Richland, Washington.

As a result of these recommendations, two rounds of personnel dosimetry processor proficiency testing were conducted for NRC by the University of Michigan (UM) from 1977–1979.[2] Fifty-nine personnel dosimetry processors, who provide dosimetry services for approximately 90% of the nuclear worker population in the U.S., voluntarily participated in these tests. Proficiency testing was conducted in accordance with the draft HPSSC/ANSI standard.

The HPSSC/ANSI Standard, "Criteria for Testing Personnel Dosimetry Performance," includes criteria for performance testing of personnel dosimetry processors who provide whole body or whole body and skin dosimetry services in eight radiation categories including x-ray, gamma, beta, neutron, and mixtures of these radiations. Criteria for testing the performance of extremity dosimeter processors and for use in evaluating the performance of pocket ionization chambers were specifically excluded from the scope of the HPSSC/ANSI Standard by the working group who wrote the Standard.

Results of the two rounds of proficiency testing of dosimetry processors indicated that improvement is needed on the part of many processors and that a significant percentage of the processors are not performing with a degree of accuracy acceptable to the NRC. Criteria for dosimetry processor performance acceptable to the NRC are specified in ANSI Standard N13.11. Results also indicated that the whole body or whole body and skin dose received by occupationally exposed personnel may often be considerably different from the dose recorded.

Because of the importance of personnel dosimetry measurements and the apparent poor performance of some processors, NRC considers that there is a need to evaluate the performance of personnel dosimetry processors periodically and to make a specific determination of competency.

Interagency coordination and cooperation was initiated very early in the program with the formation of the Interagency Policy Committee on Personnel Dosimetry (IPCPD) in 1977 to guide and coordinate correction of the dosimetry processor performance problem. NRC staff members have participated and reported to the IPCPD on the progress of this rulemaking action at all meetings. The IPCPD Committee includes representatives from: The National Center for Devices and Radiological Health [3] which is a part of Health and Human Services (HHS), the Department of Defense (DOD), the Department of Energy (DOE), the Environmental Protection Agency (EPA), the National Bureau of Standards (NBS), the NRC, the Occupational Safety and Health Administration which is a part of the Department of Labor (DOL), and the Conference of Radiation Control Program Directors which represents the States.[4] The representatives of these agencies consider the NRC to be the lead agency for the overall problem, and they plan to recommend to their various agencies that similar programs be adopted.

Industry coordination and cooperation from personnel dosimetry processors has been sought since 1977 when the Industry Overview Committee on Personnel Dosimetry was formed to monitor the progress and development of this program and to ensure that any regulatory action would be effective and appropriate to the need.

The NRC published in the **Federal Register** (45 FR 20493) an Advance Notice of Rulemaking (ANR) on March 28, 1980. The ANR fully described the results of the UM tests, discussed the need for improved dosimetry processing through rulemaking, and presented and requested comments on four methods for the operation of a proficiency testing laboratory (PTL) that would conduct performance testing against the criteria in the HPSSC/ANSI Standard. Any PTL established in accordance with one of these methods would be monitored for technical competency by the National Bureau of Standards (NBS). Licensees would be required to obtain or provide dosimetry services which satisfied criteria as established by the NRC and administrated by the PTL. The four methods for PTL operation as described in the ANR are:

1. NRC would not specify the PTL; processors and licensees would be left to their own initiatives to establish one or more PTL(s) to administer proficiency testing against the standard.
2. The PTL would be a Federal government facility managed and operated by NRC.
3. NRC would contract the services of a PTL and utilize the contractor's facilities.
4. Other government agencies experienced in laboratory testing would operate a PTL in Federal government-owned facilities.

Of the forty-six letters of comment received in response to the ANR, twenty-one letters did not state a preference for a method of operating the PTL. Three commenters felt no program at all was necessary. In the remaining 22 comment letters, one or more preferences were expressed as being acceptable for the operation of the PTL. Twenty preferences were for the various types of Federal government-controlled laboratories (methods 2, 3, or 4). Comments asked questions and commented on who should control the testing laboratory and on procedures to be used in the regulatory program, as addressed in the ANR. Other commenters discussed potential administrative, contractual, and legal problems that could result from a processor failing to achieve accredited status. These problems have been investigated by the NRC staff. There was concern regarding the values and impacts of this regulatory program. Many commenters discussed the importance of defining and requiring minimum elements of a generic quality assurance program that should be established. Several dosimetry processors who replied requested that a third round of performance testing be conducted to allow processors to be tested against the revised standard before a program becomes effective. (Such testing has been conducted, and is discussed later in this notice.) The major technical questions raised concerned the selection of dose conversion factors within the standard and the appropriateness of currently required dose measurements at three tissue depths described in NRC Form 5. These comments were examined, and a response is contained within the summary analysis of comments, which is available for review at the Commission Public Document Room (see Addresses section of this notice).

Subsequently, on April 15, 1980, the NRC staff briefed the Commission on interim actions that could be taken by NRC staff to improve personnel dosimetry processing prior to the date of the effective rule. The Commission discussed the importance of examining a processor's routine processing activities to ensure appropriate quality assurance techniques were being utilized and to determine that routine dosimetry processing was being conducted with the same processing protocols that a processor might use when participating in performance testing.

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[2] Plato, P. and G. Hudson, "Performance Testing of Personnel Dosimetry Services: Final Report of a Two-year Pilot Study, October 1977–September 1979," NUREG/CR 1064, January, 1980 University of Michigan, Ann Arbor, Michigan.

[3] Formerly the Bureau of Radiological Health (BRH).

[4] The Conference of Radiation Control Program Directors has strongly supported the development of this rule since 1973. The Conference recently advised the States of the current status of this program and encouraged individual letters to the Commission urging their strong endorsement for this rule. Several such letters have already been received.

On May 28 and 29, 1980, the NRC held a two-day public meeting with personnel dosimetry processors and other interested persons to discuss alternative methods for the operation of a PTL as stated in the ANR and to obtain comments from the dosimetry processing industry on the appropriate elements of a quality assurance (QA) program for personnel dosimetry processing.

During the comment period, a fifth method for PTL operation was identified by the National Bureau of Standards (NBS) which would be part of the National Voluntary Laboratory Accreditation Program (NVLAP) of the NBS which is a part of the Department of Commerce (DOC). The NBS, through NVLAP, could contract the services of a PTL to administer proficiency testing of processors which would utilize the contractor's facilities under currently existing NVLAP procedures. The NVLAP method would include a thorough examination of each participating processor's routine dosimetry processing and quality assurance activities through an on-site review. The NVLAP method would essentially offer a system of third party accreditation by a Federal government agency, the DOC, through the NBS.

In a letter dated December 23, 1980, the NRC staff requested the DOC to work together with NRC to establish a Laboratory Accreditation Program for Personnel Dosimetry Processors. The DOC, in accordance with NVLAP procedures and authority, stated in 15 CFR Part 7b, published NRC's request for the development of such a Laboratory Accreditation Program (LAP) in the **Federal Register** on January 29, 1981 (46 FR 9689) and requested public comment. The NRC sent a copy of the DOC's **Federal Register** Notice and a description of the NVLAP method to all known dosimetry processors, and known interested persons on February 6, 1981.

Nineteen letters of comment were received on the NVLAP method for operating the PTL as part of an accreditation program. The 19 letters were unanimous in favoring this method for operating a program for improved dosimetry. These comments are available for review at the Commission's Public Document Room (see Addresses section of this notice).

The HPSSC, which developed the draft standard that was used in the UM personnel dosimetry performance testing studies, has completed and adopted the final Health Physics Society Standard which has also recently been accepted as a final American National Standard, ANSI N13.11, by the Board of Standards Review of ANSI. Provisions will be made in the program associated with this rulemaking action to allow for changes in the ANSI standard as research or practical experience shows the need for revision.

Since the draft HPSSC/ANSI standard was significantly revised following the UM pilot study, the NRC staff authorized the UM to conduct a third round of performance testing of processors against the revised standard. This round of testing has been completed.[8] Essentially the same conditions under which processors were tested in rounds 1 and 2 were also present for this final round of testing.

Seventy dosimetry processors voluntarily participated in the third round of testing. It is estimated that these 70 dosimetry processing services develop and/or process more than 90% of the dosimeters worn by radiation workers in the U.S. Fifty-four of the 70 dosimetry processors completed these tests; seven processors dropped completely from the program during the testing period while the other nine processors submitted dosimeters but failed to return reported doses for these dosimeters to the proficiency testing laboratory at the UM. The accuracy of the irradiations performed by the UM for all radiation categories was verified by the NBS. All pilot study results have been maintained confidential by the University, and results of the pilot study are coded so that processors' names and results remain anonymous, even to the NRC.

Processors chose the categories in which they were tested. The standard provides for tests to be conducted from a total of six radiation protection categories and two radiation accident categories. The radiation protection categories include high-energy photons, low-energy photons, beta particles, neutrons plus high-energy photons, mixtures of high- and low-energy photons, and beta particles plus high-energy photons. Radiation accident categories are for high- and low-energy photons.

Participants sent the prescribed number of dosimeters to the UM where they were irradiated to doses known only to the UM and returned to the processor. The processor then determined the dose for each dosimeter and reported the results back to the UM.

The ANSI standard evaluates a processor's ability to determine the dose within a specific tolerance limit, L. Statistical criteria used in the standard include bias and precision terms. For each category, the average performance index (bias term), $\bar{P}$, and its standard deviation (precision term), S, are calculated. The performance index for a single dosimeter, P, is calculated by:

$$P = \frac{H' - H}{H}$$

where:
H = delivered quantity
H' = reported quantity

For each category, an average performance index, $\bar{P}$, and its standard deviation, S, are calculated.

A processor passes a category if

$\bar{P} + S < L$
where
a: $L = 0.3$ (accident categories)
b: $L = 0.5$ (protection categories)

The standard deviation, S, for a set of dosimeters is a measure of how results are scattered. It should be noted that the individual results can be very scattered and still have an average result very near, or even equal to, the true value. Widely scattered results have a large value of S; if the individual results are all very near the true value, S is very small.

Results from the third round of tests have been analyzed. Several dosimetry processors submitted more than one model of dosimeter for performance testing. Of the models submitted for testing, 75% of all catergories attempted were passed; thus, 25% of all category tests attempted were failed. In total, 86 different models of dosimeters were submitted for these tests. Six percent of all models of dosimeters failed every category attempted and 44% passed every category attempted. Therefore 50% of all models submitted for testing did not successfully pass all categories for which they were tested. The highest overall passing rate for all models of dosimeters among the eight radiation categories was 94% for high-energy photons in the protection dose range, and the lowest passing rate of 55% was achieved for low-energy photons in the protection dose range.

An alternative method of examining the overall performance of dosimetry processors would be to examine the performance index, P, of each of the dosimeters irradiated without regard to S. When the reported dose estimate is compared with the delivered dose, 78% of the dosimeters tested during the third round were within ±30% of the correct delivered dose. When the individual results are evaluated using criteria of ±50% of the correct delivered dose, 89% of all processed dosimeters met this criterion.

Although the identity and individual results of the dosimeter test data are confidential to the UM, the contractor reports that the categories failed in this round of testing are evenly distributed among large and small, commercial and in-house processors. NRC considers that improvement on the part of most dosimetry processors is needed and that the regulations should be amended to include competency requirements to improve the quality of dose measurements.

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[8] Plato, P. and J. Kiklos, "Performance Testing of Personnel Dosimetry Services: Final Report of Test ±3," NUREG/CR-2891. November 1982, University of Michigan, Ann Arbor, Michigan.

Regulatory Approaches Considered for the Proposed Rules

The Commission recognizes that any performance testing program can only test the ability of a processor to meet the criteria of a standard at a given point in time. A performance testing program, by itself, will not determine whether the processor actually treats its routine client's dosimeters with the same competency accorded to dosimeters received from the PTL. Therefore, it is necessary to supplement the performance testing program with checks of a processors quality assurance program regardless of the method chosen.

The Commission considered five alternative approaches for establishing a regulatory program intended to ensure improved personnel dosimetry processing. The following regulatory alternatives are presented by ranking these options from the least restrictive (no action necessary) to the most restrictive.

Alternative 1—No change in current requirements.

Alternative 2—Change in the regulation to require that licensees obtain personnel dosimetry processing from (1) processors who have successfully participated in dosimetry performance testing administered in accordance with the ANSI Standard N13.11, and (2) processors who have a documented quality assurance program. NRC would not specify the proficiency testing laboratory (PTL). The necessary elements of the QA program would be specified in the regulations. NRC inspectors would require from the licensee proof of successful performance testing and evidence that its processor's QA program complied with the regulation whether the dosimetry service was performed in-house or commercially.

Alternative 3—Change in the regulation to require that licensees obtain personnel dosimetry processing from (1) processors who have successfully participated in dosimetry performance testing administered in accordance with the ANSI Standard N13.11 by an NRC-specified testing laboratory, and (2) processors who have a documented QA program that contains necessary elements as specified in the regulation. This alternative differs from the previous alternative in that NRC would specify the PTL.

This alternative could be accomplished by either of the following approaches:

Alternative 3, Option A—NRC would obtain the services of a contractor laboratory through the competitive bidding process. NRC licensees would be required to obtain personnel dosimetry services from a processor who had successfully participated in performance testing by NRC's contractor PTL. NRC inspectors would, during licensee inspection, examine written proof provided by the licensee (1) that such performance testing was completed by the processor of licensee's personnel dosimetry, and (2) that the processor maintained a QA program that included the elements specified in the regulations.

Alternative 3, Option B—Third Party Accreditation: NRC would specify in the regulation that licensees utilize the services of personnel dosimetry processors accreditated under the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Bureau of Standards (NBS) which is a part of the Department of Commerce (DOC). NVLAP accreditation for personnel dosimetry processors would be based on three primary elements: (1) Performance testing of personnel dosimetry processors in accordance with ANSI Standard N13.11 to be performed by a laboratory contracted by NBS, (2) information collected from the personnel dosimetry processor by questionnaire, and (3) on-site inspection of routine dosimetry processing and QA techniques by NVLAP contracted assessors. The NBS would establish with NRC's approval general and specific accreditation criteria for a laboratory accreditation program (LAP) for personnel dosimetry processors which are consistent with NVLAP's established general and specific criteria currently used in programs for assessing the competency of laboratories (44 FR 12982). As appropriate, any exceptions to NVLAP accreditation criteria would be published in the **Federal Register** for public comment, and the necessary procedural steps to complete the NVLAP accreditation process for this LAP based on NRC's recommendations and the public response would be taken. The NBS, as the DOC's designee, would grant certificates of accreditation to those processors complying with NVLAP criteria. NBS, which is responsible for the on-site evaluation of laboratories under NVLAP procedures, would identify and contract with dosimetry processing experts, and it would conduct training regarding NVLAP procedures to prepare these technical experts to assess compliance of dosimetry processors with NVLAP criteria to ensure that an acceptable QA program is documented as well as implemented.

Alternative 4—Since many dosimetry processors are not NRC licensees, and since dosimeters in themselves are not radioactive but are passive monitors which measure dose received by the worker, NRC would request from the Congress the authority to license personnel dosimetry processors directly. If this authority were granted, the regulations would be appropriately amended regarding proficiency testing and quality assurance criteria acceptable to the NRC.

Alternative 5—Change in the regulation to require that licensees obtain their personnel dosimetry services from an NRC-operated or NRC-contracted dosimetry service. NRC would issue, through its laboratory, dosimeters for licensee use, and the laboratory would perform all dosimetry processing. In addition, all processing would be performed in accordance with an NRC-specified quality assurance program.

A complete analysis of these alternatives is included in the Regulatory Analysis which is available from Margaret V. Federline (see section entitled, "For Further Information Contact"), or the analysis may be examined in the Commission's Public Document Room (see section entitled, "Addresses").

Conclusions

The Commission is proposing amendments which endorse Alternative 3-Option B, which would, by amendments to the regulations, require NRC licensees to utilize the services of personnel dosimetry processors accredited by the National Bureau of Standards under the NVLAP program. The laboratory accreditation program, as previously described, would be administered by another Federal agency, the NBS, in accordance with NVLAP procedures specified in 15 CFR Part 7b. The NBS has, through a competitive solicitation process, contracted with the University of Michigan to conduct performance testing of processors against criteria specified in ANSI Standard N13.11 and plans to contract the personal services of personnel dosimetry experts to conduct on-site review of an applicant processor's routine dosimetry processing and quality assurance activities. This alternative would help correct the personnel dosimetry processor performance problem with minimum NRC staffing and resources. This program has been designed to become self-supporting from processor fees and will biennially test and evaluate the technical competency of personnel dosimetry processors performing dosimetry services for NRC licensees. It would also establish uniform minimum quality assurance criteria for routine and special dosimetry processing.

The NRC and NBS signed an Interagency Agreement on July 17, 1981, for the establishment of a Laboratory Accreditation Program (LAP) for Personnel Dosimetry Processors and a revision to that agreement on June 18, 1982 (copy available upon request). The DOC/NBS NVLAP staffs have worked with the NRC staff to develop this program within an appropriate time frame.

The Interagency Policy Committee on Personnel Dosimetry has been kept abreast and consulted about the development of the laboratory accreditation program by NBS for NRC. Representatives on the Committee have expressed agreement with the NVLAP program.

The Industry Overview Committee has worked closely with NRC and NVLAP personnel (1) in reviewing and suggesting proposed accreditation criteria for use in the development of this laboratory accreditation program, (2) in providing guidance toward selecting, training, and defining the role of NVLAP assessors who will be responsible for conducting on-site review of personnel dosimetry processors' quality assurance programs, and (3) by participation in a recent two-day public workshop sponsored by NVLAP, which was held in Washington, D.C., April 12 and 13, 1982, at NBS to discuss technical benchmarks for determining compliance of personnel dosimetry processors with NVLAP accreditation criteria.

Copies of NVLAP general and specific criteria are available in 15 CFR part 7b, and single copies are available upon request from Robert L. Gladhill (see "ADDRESSES" section). NVLAP criteria address the operation of the laboratory by focusing on the organizational structure, technical management, professional and ethical business practices, and the system for assuring the quality of test results. The criteria also generically indicate those fundamental elements necessary for the successful performance of routine services by applicants including staff competence and training, laboratory facilities and equipment, test plans, equipment calibration procedures, laboratory records, data handling procedures, and quality control checks and audits.

The availability of the laboratory accreditation program was announced by NBS/DOC in the **Federal Register** on July 28, 1983 (48 FR 34316), and supplemental information has been provided to NVLAP program applicants which details, using dosimetry processing terminology, the way general and specific criteria apply to dosimetry processors. The NVLAP/NBS staffs have worked closely with the personnel dosimetry processors, the Industry Overview Committee on Personnel Dosimetry, the Interagency Policy Committee on Personnel Dosimetry, and the NRC in developing approriate supplemental information for this LAP which was used in writing the application booklet that provides the details of NVLAP accreditation. The criteria and supplemental information establish a framework for uniformly evaluating personnel dosimetry processors, for minimizing accreditation costs, and for administering the program.

Scope of Proposed Rules

These proposed rules are specifically applicable to the processing of personnel dosimeters used to satisfy NRC requirements for determining the whole body or whole body and skin dose from X-rays, gamma, beta, and neutrons, or mixtures of these radiations for which dosimeter processing is required including film, track-etch, thermoluminescent and albedo-type dosimeters.

While the NRC recognizes the importance of assessing the accuracy of extremity dose measurements made by dosimetry processors, performance criteria for testing processors for extremity dosimeters are not available at this time. The NRC has formally requested the HPSSC to form a working group to establish such performance and quality assurance criteria for extremity dosimeter processing testing. The Chairman of the HPSSC has acknowledged the NRC's request for development of such a standard and has announced that such a group has been formed. It is estimated that a minimum of two years will be required for development and publication of a final ANSI Standard after formation of the working group. If publication of a draft ANSI Standard for public trial and use is desirable, a minimum of one and a half years would be required after working group formation. The NRC will consider appropriate amendments to § 20.202(c) when such performance criteria are available, and it is expected that such criteria will subsequently be added to the LAP for personnel dosimetry processors at the NBS.

While the NRC recognizes that some licensees use pocket ionization chambers for the purposes of recording the official whole body dose of individual employees and that this is an acceptable method of providing dosimetry services in accordance with § 20.202 of the NRC regulations, pocket ionization chambers do not require the services of a personnel dosimetry processor for interpretation or dose assessment. Appropriate calibration of pocket ionization chambers is necessary for their correct utilization. Performance criteria and calibration guidance for appropriate use and selection of pocket ionization chambers are available in NRC's Regulatory Guide 8.4, "Direct-Reading and Indirect-Reading Pocket Dosimeters," and from ANSI standards; but since these dosimeters do not require processing, they are beyond the scope of these proposed rules.

Personnel dose determinations can also be derived from survey measurements and exposure time; but, these determinations are also not included in the scope of these proposed rules.

Proposed Implementation

Processors must request application materials, complete their application forms, and submit fees to NVLAP for proficiency testing and administration which includes on-site assessment by one or more NVLAP assessors. The operational LAP and proficiency testing is currently scheduled to begin by January 1984. Copies of the LAP availability notice have been sent to all known personnel dosimetry processors and known interested persons. Processors who wish to have full benefit of additional periods of proficiency testing before NRC's final rule becomes effective (to ensure that they pass the initial testing categories they attempt) should register immediately. According to current projections, the first accreditations could be announced as soon as six months after the beginning of proficiency testing. NRC's final rule will be scheduled to become effective approximately 26 months after proficiency testing begins (February 1986) to allow processors ample opportunity to participate in performance tests administered by NBS's contractor PTL. NRC plans to act on the final rule as soon as possible after analysis of comments to this Notice of Proposed Rulemaking.

With respect to Agreement States, this item will be made a matter of compatibility because it concerns basic radiation standards.

Paperwork Reduction Statement

The application, reporting, and recordkeeping requirements contained in this proposed rule have been approved by the Office of Management and Budget (OMB); OMB approval No: 3150-0014.

Initial Regulatory Flexibility Statement

The need for these rules has been described in the Regulatory Analysis which is available for copy at the Commission's Public Document Room, 1717 H Street NW., Washington, DC 20555 or from Margaret V. Federline (see section entitled "For Further Information Contact"). The Regulatory Analysis contains a complete analysis of all technical and procedural alternatives and a statement of statutory considerations.

These rules as proposed would require NRC licensees to utilize the services of personnel dosimetry processors who are accredited under the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Bureau of Standards (NBS). Currently, NRC licensees are not required to obtain services of accredited processors because NRC does not have competency requirements for personnel dosimetry processors in its regulations. These rules are, however, being developed concomitantly with a Laboratory Accreditation Program for Personnel Dosimetry Processors being established for NRC by the NBS. It is important to note that all dosimetry processors are not NRC licensees but that nearly all commercial dosimetry processors do business with NRC licensees. It is further expected that the members of the Interagency Policy Committee on Personnel Dosimetry will recommend programs of the same nature for their respective agencies.

Approximately 4,500 licensees are currently performing personnel monitoring for their employees as prescribed in 10 CFR Part 20, § 20.202, and are maintaining radiation exposure records as specified in 10 CFR Part 20, § 20.401. NRC's contractor, the University of Michigan (UM), has estimated that there are about 90 personnel dosimetry processors in the United States who perform peronnel dosimetry services in-house or commercially. These processors were initially categorized in a June 13, 1981, letter which was updated in a November 8, 1982 letter from UM to NRC.[6] Eighty of these processors may be considered as large entities; they include seven large commercial processors, seven large private corporations, nine national laboratories, 31 nuclear power plants, 10 DOE contractors, eight military organizations, three large universities, four state public health departments, and one medical facility. These entities do not fall within the definition of "small entities," as set forth in section 601(3) of the Regulatory Flexibility Act, or within the definition of "small business" as found in section 3 of the Small Business Act, 15 U.S.C. 632, or the Small Business Size Standards in regulations issued by the Small Business Administration of 13 CFR Part 121. The remaining ten processors may, for purposes of this Regulatory Flexibility Statement, be considered "small entities" as defined in Section 601(3) of the Regulatory Flexibility Act. It was further estimated that as a group, these ten processors process only about 0.5% of all personnel dosimeters processed in the United States. It is estiamted that NRC licensees currently employ approximately 23% of the 1.4 million workers in the United States who require personnel monitoring as a result of their potential exposure to ionizing radiation.

The costs for participating in performance testing and the accreditation program, whether a processor is performing these services in-house or commercially and regardless of size, is for the purposes of this analysis approximately the same.

It has been estimated by processors that the average processor will spend approximately $7,800 on a one-time basis to prepare for the accreditation program. In most cases, the NRC believes these costs have already been incurred by processors because of the third round of testing at the UM against the revised standard and the frequent discussions and meetings that NRC staff has held with licensees and dosimetry processors in discussing the need for improved dosimetry processing and plans for NRC rules on this subject. Processors will also incur biennial costs for accreditation which include NVLAP administrative fees and costs associated with the proficiency testing administered by the PTL contracted by NBS to administer such tests in accordance with ANSI Standard N13.11. NVLAP administrative fees will include costs for (1) processing an application for accreditation, (2) conducting on-site inspection of an applicant processor's routine dosimetry processing and quality assurance techniques, and (3) for evaluating the competency and quality assurance efforts of the PTL. These biennial costs (which also include projected in-house costs to the processor) for the average processor which submits one model dosimeter for testing in eight radiation categories are estimated to be approximately $14,000 or $7,000 annually. Unlike the average dosimetry processor which participated in the third round of testing, the average "small entity" processor submitted one model of dosimeter for testing in 4 radiation categories. Projected costs for NVLAP accreditation fees, proficiency testing, and in-house costs for accreditation of a "small entity" processor total $11,800 for each 2 year accreditation period, or $5,900 annually. The Regulatory Analysis fully discusses the details of these estimates and projects that the individual processor costs could range from $6,200 to $17,200 every two years.

The total volume of business within the dosimetry processing industry is estimated at $34 million annually. The ten small personnel dosimetry processors which could be affected by this rule account for approximately 0.5%, or $170,000 of the business annually.[7] While the NRC does not know the distribution of this volume of business amont the ten dosimetry processors, an even distribution would create an average annual business of $17,000. Thus, the estimated biennial accreditation costs of $11,800 ($5,900 annual cost) for the NVLAP program is likely to have a significant economic impact on their dosimetry processing business. Complete details of these estimated accreditation costs are available in the Regulatory Analysis and in the Initial Regulatory Flexibility Analysis (available as explained under the heading "Addresses" earlier in this notice).

It is the finding of the Commission in the Preliminary Regulatory Analysis that the only acceptable alternative procedure for solving this problem is by rulemaking action and that the particular alternative proposed, third party accreditation by the National Voluntary Laboratory Accreditation Program (NVLAP), offers equal benefits for small and large processors and will almost certainly guarantee improvements in the quality of reported dose estimates. The costs necessary for compliance with this proposed regulatory program are well justified and worth the health and safety benefits that will result from improved dosimetry. The Commission has carefully examined the elements of the proposed NVLAP accreditation program and finds that differing compliance, reporting requirements, or simplification of the accreditation program are not acceptable for evaluating a processor's ability to perform accurate and consistent personnel dosimetry for NRC licensees. The NRC and NVLAP staffs have taken actions to reduce the costs associated with the accreditation of processors. The ultimate effect of a dosimetry processor not gaining accreditation could mean that it would no longer be feasible for the processor to remain in business. The accreditation process, however, offers a participating dosimetry processor considerable opportunities for correction of identified inadequacies, for repeat performance testing, and for appeal of any accreditation decisions.

In summary, the Commission has considered the impact of the NVLAP accreditation program upon the small entities affected, and has concluded that the benefits gained by workers, licensees, the general public and the NRC from providing improved personnel dosimetry services that would result from the proposed accreditation requirement and program are necessary in spite of the program's possible economic impact upon a few small entities.

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[6] Available at the Commission's Public Document Room (see section entitled Addresses) or Margaret V. Federline (see section entitled for Further Information Contact).

[7] It should be noted that only 4 of the 10 identified "small entity" processors participated in the third round of testing at the UM.

Any small entity subject to this regulation which determines that because of its size that it is likely to bear disproportionate, adverse, economic impact should apprise the Commission of this in a written comment that indicates:

(a) The processor and/or licensee's size in terms of annual receipts derived from service, number of employees, and the number of dosimeters processed annually;

(b) How the proposed regulations would result in a significant economic burden upon the licensee or processor as compared to larger licensees or processors;

(c) How the proposed regulations could be modified to take into account its differing needs or capabilities;

(d) The benefits that would accrue, or the detriments that would be avoided, if the proposed regulations were modified as suggested by the commenter; and

(e) How the regulations, as modified, would still adequately protect public health and safety and provide adequate radiation dosimetry services for U. S. nuclear workers.

List of Subjects in 10 CFR Part 20

Byproduct material, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Penalty, Radiation protection, Reporting and recordkeeping requirements, Special nuclear material, Source material, and Waste treatment and disposal.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 533 of title 5 of the United States Code, notice is hereby given that adoption of the following amendments to 10 CFR Part 20 is contemplated.

PART 20—STANDARDS FOR PROTECTION AGAINST RADIATION

1. The authority citation for Part 20 continues to read as follows:

Authority: Secs. 53, 63, 65, 81, 103, 104, 161, 68 Stat. 930, 933, 935, 936, 937, 948, as amended; 42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201. For the purposes of sec. 223, 68 Stat. 938, as amended; 42 U.S.C. 2273, § 20.401–20.408 issued under sec. 161o., 68 Stat. 950, as amended; 42 U.S.C. 2201(o). Secs. 202, 206, Pub. L. 93–438, 88 Stat. 1244, 1246 (42 U.S.C. 5842), unless otherwise noted.

2. New paragraph (c) is added to § 20.202 to read as follows:

§ 20.202 Personnel monitoring.

* * * * *

(c) After February 1986, all personnel dosimeters, except extremity dosimeters and pocket ionization chambers, that require processing to yield a dose value and that are provided to comply with § 20.101, with the requirements of paragraph (a) of this section, or with the applicable terms and conditions of any license issued by the Nuclear Regulatory Commission:

(1) shall be processed by a processor currently accredited by the National Voluntary Laboratory Accreditation Program for Personnel Dosimetry Processors of the National Bureau of Standards in accordance with accreditation criteria established in 15 CFR Part 7b; and

(2) shall be approved in this accreditation process for the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

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3. New paragraph (d) is added to § 20.401 to read as follows:

§ 20.401 Records of surveys, radiation monitoring, and disposal.

* * * * *

(d) Each licensee subject to § 20.202(c) of this part, in addition to preserving personnel monitoring records in accordance with § 20.401(c)(1) of this part, shall also preserve with these records copies of pertinent personnel dosimetry processor accreditation certificates from the National Voluntary Laboratory Accreditation Program as necessary to demonstrate compliance with § 20.202(c) after February 1986.

Dated at Washington, D.C. this 4th day of January, 1984.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

50 FR 13797
Published 4/8/85
Comment period expires 7/8/85

Licenses and Radiation Safety Requirements for Well-Logging Operations

See Part 39 Proposed Rule Making

PART 20

STANDARDS FOR PROTECTION AGAINST RADIATION

PETITIONS FOR RULE MAKING

40 FR 50327
Published 10/29/75
Comment Period expires 12/29/75
(extended to 2/12/76)

[Docket No. PRM-20-6]

NATURAL RESOURCES DEFENSE COUNCIL, INC.

Filing of Petition for Rule Making

Notice is hereby given that J. Gustave Speth, Esq., by letter dated September 26, 1975, has filed with the Nuclear Regulatory Commission a petition for rule making on behalf of the Natural Resources Defense Council, Inc., 917 15th Street, NW., Washington, D.C., requesting amendment of the Commission's "Standards for Protection Against Radiation," 10 CFR Part 20. Attached to the petition is a report prepared by Thomas B. Cochran, Ph.D., and Arthur R. Tamplin, Ph.D., entitled "Radiation Standards for Occupational Whole Body Exposure," dated September 25, 1975. The petitioners state that this report and the documents referenced therein provide the principal support for and elaboration of the petition.

The petitioners request that the Commission amend its radiation protection standards as they apply to the maximum permissible whole body dose equivalent for occupational exposure. The limits on exposure of individuals to radiation in restricted areas are set out in § 20.101 of 10 CFR Part 20. Limits regarding exposure of minors to radiation in restricted areas are set out in § 20.104 of 10 CFR Part 20. The petitioners request that the current regulations be amended as follows:

1. For individuals under the age of M, where M is to be designated by the NRC but is not less than 45 years of age, the whole body radiation exposure limit shall not exceed 0.5 rem in any calendar year and 0.3 rem in any calendar quarter.

2. For individuals equal to or greater than M years of age, a licensee may permit an individual to receive up to 3 rem per quarter whole body dose as long as the dose to the whole body shall not exceed $(0.5)(M-18) + X(N-M)$ rem, where N equals the individual's age in years, and X is calculated to reduce the cumulative somatic risks by a factor of 6 below the cumulative risks associated with exposure at 5 rem per year from age 18. It is proposed that the value X be calculated using the relative risk model as described more fully in the BEIR Report.[1]

The petitioners also request that the Commission institute hearings to determine the "as low as practicable" extent to which the exposures can be maintained below the new regulations proposed by the petitioners.

The petitioners state that the objective of their proposal is to reduce the genetic risk associated with radiation exposure at the occupational exposure level permitted by 10 CFR Part 20 by a factor of 10 and to reduce the somatic risk by a factor of 6.

A copy of the petition for rule making is available for public inspection in the Commission's Public Document Room, 1717 H Street, NW, Washington, D.C. A copy of the petition may be obtained by writing the Division of Rules and Records at the below address.

All interested persons who desire to submit written comments or suggestions concerning the petition for rule making should send their comments to the Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, on or before December 29, 1975.

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40 FR 59498
Published 12/24/75
Comment Period extended to 2/12/76

[Docket No. PRM-20-6]

NATURAL RESOURCES DEFENSE COUNCIL, INC.

Extension of Comment Period

On October 29, 1975 the Nuclear Regulatory Commission published in the Federal Register (40 FR 50327) a notice that a petition for rule making had been filed with the Commission by the Natural Resources Defense Council, Inc.

The petitioners requested that the Commission amend its radiation protection standards as they apply to the maximum permissible whole body dose equivalent for occupational exposure. The limits on exposure of individuals to radiation in restricted areas are set out in § 20.101 of 10 CFR Part 20. Limits regarding exposure of minors to radiation in restricted areas are set out in § 20.104 of 10 CFR Part 20.

The petitioners also requested that the Commission institute hearings to determine the "as low as practicable" extent to which the exposures can be maintained below the new regulations proposed by the petitioners. The petitioners stated that the objective of their proposal is to reduce the genetic risk associated with radiation exposure at the occupational exposure level permitted by 10 CFR Part 20 by a factor of 10 and to reduce the somatic risk by a factor of 6.

Interested persons were invited to submit comments on the petition by December 29, 1975. In view of the interest which has been shown on the subject matter of the petition, the Commission is hereby extending the time for filing comments.

All interested persons who desire to submit written comments or suggestions concerning the petition for rule making should send them to the Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 on or before February 12, 1976.

A copy of the petition for rule making is available for public inspection in the Commission's Public Document Room, 1717 H Street, N.W., Washington, D.C. A copy of the petition may be obtained by writing the Division of Rules and Records at the above address.

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41 FR 41759
Published 9/23/76
Comment Period expires 11/22/76
(extended to 12/22/76)

[Docket No. PRM-20-7]

NATURAL RESOURCES DEFENSE COUNCIL

Filing of Petition for Rule Making

Notice is hereby given that Richard Cotton, Esq., and Terry R. Lash, Ph.D., by letter dated August 6, 1976, have filed with the Nuclear Regulatory Commission a petition for rule making on behalf of the Natural Resources Defense Council, Inc., 917 15th Street, NW., Washington, D.C., requesting that the Commission adopt interim regulations setting standards for shallow land disposal of low-level radioactive wastes. The petitioner states that these regulations are needed to ensure adequately safe disposal of certain long-lived radioactive wastes and to assure that safe disposal methods for low-level wastes can be adopted following preparation of an environmental impact statement by NRC on its entire program for disposing of low-level radioactive wastes.

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[1] National Academy of Sciences, National Research Council, "The Effects on Populations of Exposure to Low Levels of Ionizing Radiation," Report of the Advisory Committee on the Biological Effects of Ionizing Radiations, November, 1972, p. 171.

The text of the regulations which the petitioner is proposing are set out in Appendix A to the petition. A summary of the requested action is set out in the petition as follows:

The proposed regulations would require the following:

A. *Long-Lived, Transuranic-Contaminated Wastes.* (1) The transfer of regulatory authority over long-lived transuranic wastes from the state to NRC;

(2) An immediate end to burial of long-lived transuranic wastes with only retrievable storage permitted;

(3) Payment of fees by persons that produce transuranic wastes to finance adequately safe permanent disposal;

(4) Establishment of a reporting and inspection system operated by NRC (with on-site, unannounced inspection by NRC inspectors) to assure accurate classification of transuranic wastes;

B. *Other Low-Level Radioactive Wastes.* (5) The suspension of licensing of new or enlarged burial sites until NRC establishes site selection criteria, radioactive release standards setting maximum permissible migration rates for radionuclides away from disposal sites, minimum standards for environmental monitoring programs, and standards for long-term care with mechanisms to finance such care;

(6) Establishment of minimum fees to be paid effective immediately for each cubic foot of waste buried at existing sites to assure adequate funds for long-term care;

C. *Solidification of Low-Level Radioactive Wastes Before Shipment.* (7) The solidification of all radioactive wastes before shipment to reduce the potential for release to the environment either through accident or sabotage.

The petitioners also request the Commission to undertake forthwith the preparation of a programmatic environmental impact statement pursuant to the National Environmental Policy Act of 1969 on its program for disposal of low level radioactive wastes. The petitioners state that the national program to dispose of increasing quantities of low-level wastes by shallow land burial represents a programmatic decision that must be examined in an appropriately broad programmatic environmental impact statement and that separate statements on individual sites would have difficulty considering the generic questions involved since the present need is to establish criteria for adequate disposal practices, for acceptable sites, and for the type of material such sites can properly handle.

The basis for the petitioner's request is set out in a memorandum attached to the petition "Memorandum of Points and Authorities in Support of the Natural Resources Defense Council's Petition for Rulemaking and Request for a Programmatic Environmental Impact Statement."

A copy of the petition for rule making is available for public inspection in the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C. A copy of the petition may be obtained by writing to the Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

All interested persons who desire to submit written comments or suggestions concerning the petition for rule making should send their comments to the Secretary of the Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch, by November 22, 1976.

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41 FR 52926
Published 12/2/76
Comment Period extended to 12/22/76

[Docket No. PRM-20-7]

NATURAL RESOURCES DEFENSE COUNCIL

Extension of Comment Period

On September 23, 1976, the Nuclear Regulatory Commission published in the Federal Register (41 FR 41759) a notice that a petition for rule making had been filed with the Commission on behalf of the Natural Resources Defense Council. The petitioner requested the Commission to adopt interim regulations setting standards for shallow land disposal of low-level radioactive wastes. Interested persons were invited to comment on the petition by November 22, 1976.

In view of a recent request by Nuclear Engineering Company that the comment period be lengthened, the Commission is hereby extending the time for filing comments.

Accordingly, all interested persons who desire to submit written comments or suggestions concerning the petition for rule making should send them to the Secretary of the Commission, Attention: Docketing and Service Branch, United States Regulatory Commission, Washington, D.C. 20555 on or before December 22, 1976.

A copy of the petition for rule making is available for public inspection in the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C. A copy of the petition may be obtained by writing the Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

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43 FR 27016
Published 8/21/78
Comment period expires 10/20/78

[Docket No. PRM-20-6A]

ROSALIE BERTELL

Filing of Petition for Rule Making

Notice is hereby given that Dr. Rosalie Bertell, by letter dated July 18, 1978, has filed with the Nuclear Regulatory Commission a petition for rulemaking requesting amendment of the Commission's "Standards for Protection Against Radiation," 10 CFR Part 20.

The petitioner requests the Commission to amend its standards for protection against radiation as they apply to the maximum whole body dose equivalent for occupational exposures to ionizing radiation. The petitioner states that:

> This amendment would have the same effect measured by the reduction of the individual's biological ability to cope with chronic and malignant disease, as would be achieved by reducing the current maximum permissible whole body dose equivalent for occupational exposure by a factor of fifty.

The petitioner also requests that 10 CFR Part 20 contain specific mention of those diseases which indicate above normal susceptibility to leukemia and/or radiation damage as reported in the journal article and testimony attached to the petition. The petitioner states also that:

> Preemployment screening and notification of employees when such indicator diseases are diagnosed should be mandatory. Work in restricted areas should be curtailed or eliminated for the susceptible individuals.

The petitioner requests further that the rulemaking hearing convened in response to this petition be consolidated with that requested by the Natural Resources Defense Council, Inc. (PRM-20-6). The petitioner also requests that the date for a formal adjudicatory hearing to reduce Federal radiation standards be set within 6 months of receipt of this petition.

A copy of the petition for rulemaking is available for public inspection in the Commission's Public Document Room, 1717 H Street NW., Washington, D.C. A copy of the petition may be obtained by writing the Division of Rules and Records at the below address.

All interested persons who desire to submit written comments or suggestions concerning the petition for rulemaking should send their comments to the Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, on or before October 20, 1978.

44 FR 43541
Published 7/25/79

[Docket No. PRM-20-7]

Natural Resources Defense Council, Inc.; Action on Petition for Rulemaking

Please take notice that the Nuclear Regulatory Commission (NRC) has denied a portion of a petition for rulemaking submitted by letter dated August 6, 1976 by the Natural Resources Defense Council, Inc. (NRDC), 2345 Yale Street, Palo Alto, California 94306. The petition requested that the NRC immediately adopt interim regulations setting standards for shallow land disposal of transuranic (TRU) and other low-level radioactive waste as well as prepare a broad programmatic generic environmental impact statement (GEIS) on low-level waste disposal.

A notice of filing of the petition, Docket NO. PRM-20-7, was published in the Federal Register on September 23, 1976 (41 FR 41759) and the public was invited to file comments on the petition within 60 days of publication of notice. (The comment period was later extended to 90 days.) Fourteen of the fifteen responses from industry and the States that were received by the NRC recommended denial of the petition. In addition, the original petitioner (NRDC) filed an "analysis" and comments on the other comments received by the Commission.

Analysis of the issues and points raised by the petition was performed by the NRC staff when the petition was initially reviewed. At that time, the NRC staff concluded that no compelling potential health and safety hazard existed to warrant immediate NRC reassumption of regulatory authority from Agreement States, or immediate implementation of interim regulations as proposed by the petitioner. (NRC staff rationale for their decision regarding the need for immediate action as proposed by the petitioner is contained in the material presented in *NRC Staff Position on Petition*, which follows in this Notice.) A broad, flexible program for the orderly development of comprehensive regulations governing the management and disposal of low-level radioactive waste by shallow land burial or other alternative methods was initiated and subsequently announced in the Federal Register on December 7, 1977 (42 FR 61904). This program is currently in progress. The regulations and supporting environmental impact statements are scheduled to be issued for public comment in 1980 and will address disposal of all nuclides, including transuranic nuclides.

The Commission believes that a separate GEIS on low-level waste disposal is neither required by the National Environmental Policy Act of 1969 (NEPA) nor necessary for the development of the NRC program. It is intended that the environmental impact statements and other technical documentation being developed to support the forthcoming regulations will be of sufficient scope to address the major issues that would be included in the petitioner's proposed programmatic GEIS. The issues and points raised in the petition and in the petitioner's proposed GEIS outline are, however, being considered by NRC staff as input to their development of waste management regulations and supporting environmental impact statements.

The petitioner has been a participant in the advisory panel for the development of NRC's proposed radioactive waste classification system. In addition, the requirements stated in the recent NRC request for proposals (RS-NMS-79-026) for assistance in the development of the environmental impact statement (EIS) to guide and support the proposed regulation on low-level waste disposal, 10 CFR Part 61, include many of the issues and points raised by this petition.

The remaining sections of this notice include a summary of the petition, a summary of the public comments on the petition, the NRC staff position on the petition, a background discussion of the NRC Waste Management Regulations development effort, and a summary of the NRC staff response to the NRDC "Allegations of Fact."

Summary of Petition

Briefly, the regulations proposed by the petitioner would have required the following:

Long-Lived Transuranic-Contaminated Waste

—The transfer of regulatory authority over long-lived transuranic waste from Agreement States to NRC; (7)[1]

—An immediate end to disposal by burial of long-lived transuranic waste with only retrievable storage permitted; (5)

—Payment of fees by persons who produce transuranic waste to finance adequately safe permanent disposal; (6)

—Establishment of a reporting and inspection system operated by NRC (with on-site, unannounced inspection by NRC inspectors) to assure accurate classification of transuranic waste; (3)

Other Low-Level Radioactive Waste

—The suspension of licensing of new or enlarged burial sites until NRC establishes site selection criteria, radioactive release standards setting maximum permissible migration rates for radionuclides away from disposal sites, minimum standards for environmental monitoring programs, and standards for long-term care with mechanisms to finance such care; (10)

—Establishment of minimum fees to be paid (effective immediately) for each cubic foot of waste buried at existing sites to assure adequate funds for long-term care; (4)

Solidification of Low-Level Radioactive Waste Before Shipment

—The solidification of all radioactive waste before shipment to reduce the potential for release to the environment either through accident or sabotage. (7)

The petitioner also requested that the Commission immediately prepare a GEIS on the Commission's program for disposal of low-level radioactive waste. The petition stated that a national program for disposal of low-level waste by shallow land burial represents a major programmatic decision that must be examined in an appropriately broad programmatic GEIS. It also stated that separate statements on individual sites would have difficulty considering the generic questions involved since the present need is to establish criteria for adequate disposal practices, for acceptable sites, and for the type of material that the disposal sites can properly handle.

The petition was accompanied by an appendix suggesting regulation language as well as a "Memorandum of Points" discussing the basis for the petition. A summary of the Memorandum was included in the petition in the form of ten "allegations of fact" (petitioner's wording). The appendix also included suggestions for the scope and development of the proposed GEIS.

A copy of the petition (Docket No. PRM-20-7) with attachments is available for public inspection in the Commission's Public Document Room (PDR) located at 1717 H Street, NW., Washington, D.C. 20555. Copies of comments on the petition are also available for inspection in the PDR.

Summary of Public Comments

Overall response to the petition was that it not be adopted as proposed. Of the 15 commenters (all industrial or state groups), only one consistently supported the petitioner's recommendations, as stated. In addition, the original petitioner (NRDC) filed comments and an "analysis of comments" on the other comments received by the Commission.[2]

Proposed Interim Regulations. The comments received did not generally support the necessity of immediate adoption of interim regulations. (The total number of public comments received on each of the NRDC-recommended regulations are listed in the *Summary of Petition* above.) With exception of the NRDC analysis of the comments, little rationale was given to support interim regulations. Ten commenters stated that there was no demonstrated public health and safety risk with present practices and thus there was no justification or legal basis for the interim regulations.

Two of the commenters responded favorably to NRDC's proposed regulations for an immediate end to non-retrievable TRU waste disposal, and for payment of fees by producers of waste for long-term care. Two of the commenters supported the proposed regulations, with one commenter noting the toxicity and long half-lives of TRU.

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[1] Indicates the total number of public comments received on each of the NRDC recommendations listed.

[2] Material in the analysis that was not directly linked to remarks by another commenter was treated by the NRC staff in the same manner as other comments on the petition.

One other commenter suggested that an amendment to the one disposal license [9] permitting burial of TRU waste would be more workable than a rulemaking action. The two negative commenters believed that the toxicity and long half-lives of TRU nuclides required careful handling but there was no urgency to the matter. They stated that before regulations are promulgated, a study should be conducted to define TRU waste and the methods by which TRU waste would be disposed. The commenters generally agreed that the producers of waste should be responsible for the costs accrued, but that setting fees by regulation was unworkable.

The commenters were generally negative on NRDC's proposed regulations for transfer of TRU licensing from the Agreement States to the NRC, for suspension of licensing of new or enlarged sites until certain site criteria were adopted, and for solidification of all low-level waste before shipment. The commenters felt that the uniformity allowed by Federal control was a good idea, but that there was no reason to disrupt the Agreement State program. The commenters also thought that suspension of licensing activities was unnecessary and might not be in the public interest. Seven commenters responded to the proposal for solidification requirements, stating that shipment of present quantities of liquid low-level waste is not a major risk and is already regulated. They also stated that many factors should be considered before NRC requires solidification of waste—i.e., concentrations, quantities, probabilities of release, consequence, packaging, costs and benefits.

NRDC "Allegations of Fact." Each of the ten allegations of fact made by the petitioner in support of the petition generally received from one to four comments, not including the petitioner's analysis. The commenters remarked that seven of the allegations of fact were inaccurate or distorted. One allegation received no comments. Two of the allegations of fact—(1) ERDA has prohibited burial of government-TRU waste, and (2) the Atomic Energy Commission (AEC) proposed but did not finalize regulations for commercial-TRU waste burial—were accepted as true. All that commented on these two allegations of fact (except the petitioner) felt that the actions discussed provided insufficient justification for the petition. (See Appendix A for a summary of NRC staff response to the "Allegations of Fact.")

Low-Level Waste Generic Environmental Impact Statement. Comments on the necessity of a GEIS were divided, with one commenter supporting and three opposing. The supportive commenter felt that a GEIS should be done because low-level waste has significant environmental impacts and a comprehensive evaluation had not been done to date. Those opposing stated that there was no need or basis for a GEIS or thought that such a statement should be part of the waste management GEIS being prepared by the Energy Research and Development Administration (ERDA). (For the reader's information, on October 1, 1977, ERDA was combined with other government agencies to form the Department of Energy (DOE). In April 1979, DOE published a GEIS entitled "Draft Environmental Impact Statement on Management of commercially Generated Radioactive Waste" (DOE/EIS-0046-D). This GEIS focuses on alternative methods for permanent disposal of commercially-generated high-level and TRU waste.

NRC Staff Position on Petition

To recapitulate and consolidate, the NRDC petition essentially requests five kinds of actions from NRC:

1. Reassert regulatory authority for TRU waste from Agreement States and limit TRU waste disposal to a retrievable form.
2. Invoke a moratorium on new or enlarged burial site licensing pending the establishment of certain requirements.
3. Establish a perpetual-care find by regulation.
4. Restrict transportation of low-level waste in liquid form.
5. Prepare a generic environmental impact statement.

The NRC staff position on these areas, in which the Commission concurs, is as follows:

TRU Waste Disposal—Under Section 274c(4) of the Atomic Energy Act of 1954, as amended NRC must determine existence of a hazard or potential hazard prior to the reassertion of regulatory authority from Agreement States. A somewhat similar finding must be made for the immediate implementation of regulations governing low-level waste disposal or prohibiting TRU waste disposal by shallow land burial. The staff does not believe that current operation of burial grounds in Agreement States would justify the necessary finding that a hazard exists or potentially exists for exercise of this statutory authority. (Earlier NRC publications, such as the NRC Task Force Report, the Federal Register Notice announcing the Task Force Report (42 FR 13366, March 10, 1977), and the Federal Register Notice announcing the NRC low-level Waste Management Program (42 FR 61904, December 7, 1977), have contained similar statements.) NRC has already initiated a comprehensive program for development of regulations governing the management and disposal of all types of radioactive waste, including TRU waste. Although it is conceivable that the NRC could initiate an effort to develop temporary "interim" rules as suggested by the petitioner, NRC staff believes that, as a practical matter, well planned "interim" rules could not be prepared on a schedule much different than current, ongoing schedules for regulations development. To do so would delay placing the broader, more comprehensive regulations currently under development into effect. It is for these latter regulations that there is a demonstrated need.

Nonetheless, an interim short-term period will elapse before executive and legislative decisions are made on the issues of management and disposal of radioactive waste and prior to the completion of the regulations currently under development by NRC. The NRC staff notes the concern of the petitioner, the public, and others regarding the safe disposal of TRU and other waste and is investigating the effects of continued short-term TRU burial as well as possible alternatives—such as retrievable storage—to TRU waste burial. In any case, the staff believes that retrievable storage procedures similar to procedures used today by DOE for storage of TRU waste may be necessary for certain types of waste defined by the waste classification regulation when this regulation is adopted.

Today, only the site operated by the Nuclear Engineering Company, Inc. (NECO) and located in the center of the Hanford Reservation near Richland, Washington, accepts TRU-contaminated materials in concentrations greater than ten nanocuries per gram for burial in soil. The disposal site is located on land leased from the Federal Government to the State of Washington, who then subleases a portion of the leased land to the disposal site operator. At the commercial site, the disposal of special nuclear material (SNM), including plutonium, is regulated by NRC. As Washington is an Agreement State, the State of Washington regulates the disposal of source and byproduct material (including TRU isotopes other than plutonium).

The limited burial to date of TRU-contaminated waste in the middle of the Hanford Reservation minimizes any potiential future problems since geohydrological, meteorological, and ecological factors regarding the overall Hanford Reservation are well investigated and documented; and extensive monitoring programs are conducted by DOE in addition to those conducted by NECO. No public health and safety problems have been identified with the operation of the commercial site. Quantities of TRU materials delivered to the commercial disposal site are currently small and, due to executive decisions deferring reprocessing of spent power reactor fuel, should remain small. Total inventories of commercial TRU waste buried at the site as well as inventories that are expected to be delivered in the next few years are small compared to the inventories already existing on the surrounding Hanford Reservation.

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[9] The only commercial burial site currently disposing of small quantities of TRU waste by shallow land burial is the site operated by the Nuclear Engineering Company, Inc. (NECO) and located in the center of the Hanford Reservation near Richland, Washington.

The continued burial of plutonium-contaminated waste at the commercial disposal site is under independent review by the NRC licensing staff in considering the renewal of NECO's SNM disposal license at Hanford. Washington is undergoing a similar review for wastes contaminated with other TRU isotopes. A decision whether to allow or prohibit the burial of TRU waste at that site will be made in connection with these licensing reviews, Discussions between DOE, the State of Washington, NECO, and NRC staff have been held regarding the possible discontinuance of TRU burial at the Hanford commercial site. NRC staff understands that the State of Washington is considering action, under the State's authority as site landlord, to discontinue disposal of TRU waste. Any action taken at the site regarding disposal of TRU waste will be closely coordindated between NRC and State staff.

An alternative action (to burial) is acceptance for storage of commercial TRU waste by the Federal government (e.g., DOE), with a charge levied on the waste generator to cover costs of storage, retrieval, repackaging (if necessary), transport, and ultimate disposal. In their report to the President ("Report to the President by the Interagency Review Group on Nuclear Waste Management," TID-29442, March 1979) recommending a national plan for radioactive waste disposal, the Interagency Review Group on Nuclear Waste Management (IRG) recommended that TRU waste should be isolated from the biosphere in a manner similar to that used for isolation of high level waste. The IRG also recommended that legislation be enacted to extend NRC licensing authority to cover DOE activities regarding new DOE facilities for disposal of TRU waste.

NRC is currently developing a waste classification regulation to determine the types of low-level radioactive waste material that can be disposed of by various disposal methods. (See Appendix A for more information.) This regulation is scheduled to be published for public comment in 1980. As a result of the regulation, certain types of waste will require retrievable storage pending transfer to a repository for final disposal. It is expected that retrievable storage of such waste would be accomplished in a similar manner as that used today for the storage of government-produced TRU waste.

Licensing of New or Enlarged Burial Sites. NRDC interprets the Atomic Energy Act as requiring a moratorium on NRC and Agreement State licensing of new burial sites and expansions of existing sites pending promulgation of Commission regulations governing shallow land burial. This request is based on NRDC's findings that current NRC and State regulation is inadequate as demonstrated by waste migration and other incidents, In addition, NRDC argues that the Commission must regulate by promulgating regulations. Finally, NRDC relies on Section 274(c)(4) of the AEA to assert that the Commission must require Agreement States to apply NRC reguations.

The incidents described by NRDC have been investigated by the NRC staff. In its opinion they do not constitute health or safety hazards to the public which warrant Commission termination of an Agreement State Program pursuant to Section 274j of the AEA, or a Commission moratorium on its own licensing activities. Furthermore, NRDC is incorrect in its legal argument regarding the need for Commission regulations. It is a well-established principle of administrative law that an agency has discretion to proceed by regulation or adjudication. *SEC* v. *Chenery Corp.*, 322 U.S. 194, 203 (1947). This principle is especially applicable to the Commission because Congress has granted it unusually broad discretion to carry out the Atomic Energy Act. *Vermont Yankee Nuclear Power Corp.* v. *NRDC*, 55 L. Ed. 2d 450, 474 n. 13 (1978); *Siegel* v. *AEC*, 400 F. 2d 778, 783 (D.C. Cir. 1968). Therefore, the Commission is not required to impose a moratorium on the licensing of low-level waste disposal pending the promulgation of regulations. Finally, section 274c(4) of the AEA does not support NRDC's assertion that the Commission must impose its regulations on Agreement States to satisfy the Commission's "duty" to make a continuing determination that State programs are not leading to hazardous disposal. Section 274c(4) imposes no such duty of continuous Commission review. That section allows continuance of NRC authority over the disposal of hazardous materials at the time the Commission enters into a State Agreement if the Commission by regulation or order determines that continued Federal control is necessary. Furthermore, NRDC's "dual authority" theory is contrary to the recent decision in *NRDC* v. *NRC*, 8 ELR 20163, 20164 (D.C. Cir. Jan. 6, 1978), in which the Court held the Commission retains no residual authority over individual licensing actions taken by Agreement States.

The staff believes that licensing new or enlarged burial grounds on the basis of need is an option which, for continued assurance of protection of the public health and safety, should not be foreclosed. There is a continuing production of low-level waste at hospitals, universities, laboratories, reactors, etc., that requires disposal and the only currently available disposal method is shallow land burial. Until the regulations governing shallow land burial and alternative disposal methods are established, applications for new or enlarged disposal sites will be handled on a case-by-case basis. Any new licenses that are issued by NRC will be qualified by the provision that the licenses may be modified as new criteria and regulations are developed. Because of NRC's close liaison with the Agreement States, NRC staff expects that the States will initiate similar actions. Every Agreement State's radiological health program is reviewed annually to ensure that it is adequate for the protection of the public health and safety and that it is compatible with similar NRC programs.

Long-Term Care and Funding. Issues related to long-term care and funding of commercial waste disposal sites are being addressed by NRC. The staff believes that such issues, some of which were discussed by the petitioner, can be best resolved within the framework of the existing NRC low-level waste management and regulatory development program. In accordance with the program, NRC has initiated a number of studies to develop funding standards, procedures, and predictive tools.

One particular series of studies has been contracted to determine criteria and standards regarding safety and costs related to decommissioning nuclear fuel cycle facilities. To date, results of studies on a fuel reprocessing plant and a pressurized water reactor have been published. These reports, along with other ongoing studies on a boiling water reactor and facilities associated with the front end of the nuclear fuel cycle, will provide useful data to the regulatory development effort. Of more specific significance to the effort is a study underway to evaluate the safety and costs related to decommissioning a low-level waste burial site.

This study, scheduled for completion this year, has a five-fold technical emphasis.

1. Provide technical bases for the establishment of operating criteria for existing burial grounds;
2. Identify long-term care requirements for burial grounds;
3. Estimate future financial needs for the decommissioning of burial grounds and evaluate bases for the establishment of financial structures for long-term care of burial grounds;
4. Evaluate potential record keeping needs; and
5. Evaluate the environmental monitoring needs.

NRC also plans to address through our regulations development effort alternative organizational roles involving low-level waste site regulation, site operation, site ownership, financial liability, decommissioning and inspection.

For use in the interim period prior to promulgation of the low level waste regulations, NRC's Division of Waste Management, Office of Nuclear Material Safety and Safeguards, has prepared a technical position on requirements on low level waste burial ground site closure and stabilization. This technical position is being incorporated into the licenses for the three disposal facilities currently open. A copy of this technical position is available for public inspection in the Commission's PDR.

One of the alternative methods to provide long-term funding is, as recommended by the petitioner, the establishment of a special fund based upon a cubic foot charge by NRC regulation. (The NRC Task Force recommended a Federally-administered long-term care fund in NUREG-0217.) However, the establishment by NRC of a long-term care fund through fees based upon volume of materials buried poses difficult questions of law. Although fees for use of property may be established between landlord and tenant, as is currently the case, to order a fee per unit volume of waste by Commission regulation and to establish an earmarked fund would require Congressional authorization.

A federally mandated fee per unit volume of waste that is not a product of the landlord/tenant contract, would be in essence a tax requiring legislative enactment. (See *Federal Power Commission* v. *New England Power Co.*, 415 U.S. 345 [1974]; *National Cable Television Association Inc.* v. *United States*, 415 U.S. 336 [1974].) The establishment of a special fund based upon such a tax would also require special legislation.

Based on landlord/tenant (State/site operator) contracts authorized by State law, all six States containing commercial burial sites collected disposal fees from the site operator on a per-cubic-foot basis and place the collected fees into a State fund established for long-term care of the sites. Three sites are presently closed and not collecting fees. (A specific fund for long-term care of the Sheffield, Illinois site was established in 1977 in Illinois. Illinois previously chose to assign the collected fees into the State general Fund.) However, as noted in NUREG-0217, no national standards are available by which States can evaluate the adequacy of existing long-term care funds or collection rates, evaluate proposed changes to long-term care charges, or evaluate amounts that might be needed for corrective actions if major problems develop in site operations. Development of such standards is being addressed in the studies previously discussed as well as other staff efforts.

Transportation of Liquid Low-Level Waste. In the request for regulations prohibiting transportation of all liquid waste, the petitioner observes that the liquid form increases the potential mobility of the waste material. However, the existing regulations adopted by the NRC and the Department of Transportation (DOT) [4] specify the types and limiting concentrations of all radioactive material, including liquids, acceptable for shipment as well as the packaging requirements. As would be expected, materials of greater hazard or mobility are regulated more stringently than materials of lesser hazard or mobility.

For example, liquid radioactive material in Type A quantities must be packaged in or within a leak-resistant and corrosion-resistant inner containment vessel. The packaging must be adequate to prevent loss or dispersal of the contents of the inner container vessel if the package was subjected to a prescribed 30-foot drop test. Either enough absorbent material must be provided to absorb at least twice the volume of the liquid contents or a secondary containment vessel must be provided to retain the radioactive contents under normal conditions of transporting, assuming the failure of the inner primary containment vessel. Quantities of radioactive material greater than Type A limits can be transported only in Type B packaging, which is designed to more stringent standards such as survivability under certain hypothetical accident conditions. Other, less stringent standards apply to material, such as low specific activity material, containing low concentrations of radioactivity.

The few cases of shipment of low-level liquid waste do not represent a hazard to the public health and safety. Policies in effect at the commercial disposal sites require that only solid waste material may be buried. Liquids, except for liquid scintillation vials, must be solidified before burial.

Liquid scintillation vials are typically small glass vials (about an inch in diameter by a few inches high) containing small quantities of radioactive material (microcuries per liter) in an organic solution. The vials are transported to disposal sites in drums containing enough absorbent material to absorb at least twice the volume of the liquid contents. Additional processing prior to disposal may be performed at the disposal sites.

As part of a general review of the existing regulations and procedures for the packaging and transportation of radioactive materials, the NRC initiated in June 1975 the development of an "Environmental Impact Statement on the Transportation of Radioactive Material by Air and Other Modes." The final statement (NUREG-0170) was published in December 1977. The statement covered the transportation of all types of radioactive material—from spent fuel to low specific activity material—and indicated that transportation of radioactive material is being conducted under the present regulatory system in an adequately safe manner.

Based on this statement and the staff's continuing review of potential problems associated with transport of radioactive material, the staff concludes that no health and safety problem currently exists to warrant the immediate establishment of regulations prohibiting transportation of liquid waste. Present practices of solidifying and disposing of radioactive waste are being addressed as part of the ongoing NRC low-level waste program.

Low-Level Waste GEIS. The NRC staff believes that issuance of a separate programmatic GEIS as proposed by the petitioner is in this case neither required by NEPA nor necessary to conduct NRC's existing program for study and development of regulations for low-level waste disposal. The arguments relied upon by NRDC do not compel a GEIS. The facts do not warrant it. At this time, the Commission independently licenses only one such facility located near Sheffield, Illinois.[6] Five Agreement States license five other low-level waste disposal sites pursuant to their own authorities. (At two of these five sites, Washington and Barnwell, South Carolina, NRC issues a Special Nuclear Material (SNM) license.) Contrary to NRDC's assertion, these State actions are taken pursuant to their own authorities and not under authority delegated by the Commission. *Natural Resources Defense Council* v. *Nuclear Regulatory Commission,* supra. Furthermore, NRDC's theory of continuing NRC authority over licensing actions by Agreement States leads to dual jurisdiction contrary to the clear expression of Congressional intent in enacting section 274 of the Atomic Energy Act. S. Rep. No. 870, 86th Cong., 1st Sess. 9 (1959). Dual jurisdiction was also explicitly rejected by the Court in *NRDC* v. *NRC,* supra, which held that the Commission has no residual authority over individual licensing actions taken by Agreement States. Consequently, the only *federal* licensing actions by the Commission regarding shallow land burial of low-level waste are associated with the licensing of the Sheffield facility and the SNM licenses at Hanford and Barnwell. Any proposed licensing actions for these facilities will be assessed by NRC in accordance with 10 CFR Part 51, and if necessary, an EIS will be prepared.

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[4] In the United States, the DOT and the NRC share primary regulatory authority for transport and packaging for transport of radioactive material. The DOT and the NRC partition their overlapping responsibilities by means of a Memorandum of Understanding, last issued in March 1973, between DOT and the Atomic Energy Commission (AEC), the predecessor of NRC.

The technical studies being conducted and environmental impact statements that will be prepared and published to guide and support NRC's regulatory development effort will form a sufficiently large informational and decisional base to obviate any need for a separate GEIS. The EIS used to guide and support the proposed low-level waste regulation will, in part, analyze shallow land burial in the context of alternative disposal methods for low-level waste. Input to the analysis is being provided by a NRC-contracted study of alternative disposal methods. This study is identifying viable alternative disposal methods and submitting to further detailed study alternative methods determined on the basis of a preliminary screening effort. Preliminary results of the study to date have been published in a status report entitled, "Screening of Alternative Methods for the Disposal of Low-Level Radioactive Waste" (NUREG/CR-0308), October 1978.

The alternatives study may yield several acceptable alternative methods for low-level waste disposal. As part of the NEPA process, shallow land burial must be considered within the context of other alternatives and their technical uncertainties. However, technical criteria and requirements for disposal by shallow land burial are needed to meet regulatory requirements for existing and any new shallow land burial sites. As guided by the EIS, NRC plans to develop technical criteria and requirements for shallow land burial and for identified viable alternatives.

NRC staff is considering the issues raised in the petition and in the petitioner's proposed GEIS outline in their development of the proposed low-level waste disposal regulation and guiding EIS. The request for proposal (RS-NMS-79-026) for this EIS includes many of these issues. In addition to this input, NRC staff is considering public input from an Advance Notice of Proposed Rulemaking which was published in the Federal Register (43 FR 49811) on October 25, 1978, to invite public comments and suggestions on the scope, content, and issues to be addressed in the EIS. The petition and GEIS outline are also being considered as input to NRC's development of the waste classification regulation and guiding EIS. An Advance Federal Register Notice of Proposed Rulemaking on the waste classification EIS is expected to be published shortly.

Further information regarding NRC's program to develop low-level waste regulations is contained in Appendix A.

Dated at Washington, D.C. this 16th day of July 1979.

For the U.S. Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

Appendix A.—Background—NRC Regulatory Development Effort

NRC Task Force. Issues related to Federal versus State regulation of commercial radioactive waste burial grounds were addressed in an NRC Task Force Report ("NRC Task Force Report on Review of the Federal/State Program for Regulation of Commercial Low-Level Radioactive Waste Burial Grounds," NUREG-0217, March 1977; NUREG-0217 Supplement 1, October 1977). These issues were raised by the General Accounting Office (GAO), the Joint Committee on Atomic Energy (JCAE), and the House Committee on Government Operations. The NRDC petition was received after the formation of the Task Force and referenced the issues raised by the above organizations. The petition—along with the publications and recommendations of a wide range of Congressional, technical, industrial, public, and governmental groups—provided input to the Task Force study and was referenced in the Task Force Report.

After concluding that the States through their regulatory programs have adequately protected the public health and safety, the Task Force made a number of recommendations regarding Federal versus State regulation and other related issues currently affecting commercial burial ground regulation and operation. These recommendations included accelerated development of a specific regulatory program for low-level waste disposal including regulations, standards, and criteria; and studies to identify and evaluate the relative safety and impacts of alternative low-level waste disposal methods.

The staff subsequently published a program plan for low-level waste management entitled "NRC Low-Level Radioactive Waste Management Program" (NUREG-0240, September 1977), including technical studies to prepare a regulatory base, development of regulations, criteria, and supportive EIS's and development of criteria and procedures for applicants to prepare license applications and for NRC to make uniform and timely licensing decisions. To formulate the program, the staff considered the Task Force recommendations; public comments on the Task Force Report; data gleaned from review of technical documents and participation in conferences, meetings, and discussions attended by industrial, state, and public organizations; and considerations of the points and recommendations contained in the petition, comments on the petition, and other correspondence and documents. Periodic updates of NUREG-0240 are planned and the first update is expected in 1979. The progress made to date in NRC's program of technical study and regulation development will be summarized in the update and further refinements to the program discussed.

Radioactive Waste Classification Regulation. As noted in NUREG-0240, NRC plans to propose a radioactive waste classification regulation which will stipulate the kinds and quantities of radioactive material that can be disposed of by various methods. The regulation will also outline general licensee requirements (e.g., confirmatory measurements, record-keeping, inspections) that will ensure proper classification of wastes. NRC is initiating a contractual effort to prepare an environmental impact statement (EIS) to guide and support the waste classification regulation. An Advance Notice of Proposed Rulemaking will soon be published in the Federal Register to request advice, suggestions, and comments on the issues, scope, and content of the EIS used to guide the regulation. The proposed regulation, draft EIS, and draft regulatory guide which will provide assistance to licensees in complying with the regulation are currently scheduled for publication in 1980.

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[6] The disposal facilities located near Sheffield, Illinois; Beatty, Nevada; and Hanford, Washington were all originally licensed by AEC. Since the time that these three facilities were originally licensed, both Nevada and Washington have become Agreement States.

As a starting point for the waste classification regulation and guiding EIS, NRC contracted a waste disposal classification system study which was intitiated, in part, to address the public comments received on a rule proposed by the AEC in 1974 to prohibit the burial of TRU-contaminated commercial waste. In this proposed rule, commercial TRU waste in concentrations greater than 10 nanocuries per gram of material would have been consigned to retrievable storage facilities operated by the Federal government pending the development of a facility for the ultimate disposition of the waste. However, numerous problems (e.g., poor justification for the 10 nanocurie per gram limit, no cost-benefit analysis, no accompanying regulatory guides) were identified by persons commenting on the proposed rule, and the rule was never adopted by the AEC for commercial waste.

A ten nanocurie per gram TRU burial limit, however, was adopted by AEC in 1970 for government-produced radioactive waste and this limit is still in effect at sites operated by the Department of Energy (DOE). An investigation is underway in DOE to redefine the concentration levels at which government-produced TRU nuclides may be disposed of by shallow land burial. Some modification of the interim ten nanocurie per gram limit may result based on this investigation.

In the current waste classification study contracted by NRC, TRU waste is *not* classified as *separate* waste category. Instead, concentrations of individual radionuclides, including TRU nuclides, are classified according to the disposal requirements of the radionuclide concentration. In the study, it was determined that all radioactive waste disposal methods can be placed into one of three generic categories.[1]

1. Isolation in a repository or disposal by other means providing a high degree of isolation;
2. Confinement for a period of time with controlled, predictably low release rates; and
3. Discharge directly into the biosphere in a manner similar to that utilized for municipal non-radioactive trash.

The waste disposal categories are not limited to specific disposal methods. However, each category implies general time periods for confinement—e.g., thousands of years for category 1, hundreds of years for category 2, and essentially immediate release for category 3.

A classification methodology was developed which invloves identifying a set of exposure events at model waste disposal facilities, describing potential radionuclide transport to man, and calculating limiting concentrations or inventories of radionuclides in waste that may be placed in the model disposal sites to ensure that specified dose guidelines are not exceeded. A status report on the waste classification methodology and applications has been published ("A System for Classifying Radioactive Waste Disposal—What Waste Goes Where?", NUREG–0456, June 1978). A Federal Register notice (43 FR 36722–36725) was issued to announce the availability of the document and to request public comments on the in-progress study. Comments received by the NRC will be incorporated into the further development of the classification system, the completion of the study, and the development of the waste classification regulation. An updated report on the classification system study is planned for publication in 1979.

Rule Making Actions. The licensing requirements for management and disposal of the types of waste defined by the waste classification regulation as well as the technical requiremets for various disposal methods will be addressed in two other rule making actions. A proposed regulation (10 CFR Part 60: "Disposal of High-Level Waste in Geologic Repositories") plus a supporting EIS governing the management and disposal of high-level waste are scheduled for publication in a draft form during 1979. Additionally, NRC is now initiating a contractual effort to prepare an EIS to guide and support the development of a proposed regulation 10 CFR Part 61, entitled "Management and Disposal of Low-Level Radioactive Waste." An Advance Federal Register Notice of Rulemaking (43 FR 49811) was issued on October 25, 1978 to request public comments on the contents and scope of the EIS and proposed low-level waste disposal regulation, which are both scheduled to be published for public comment in 1980.

The proposed low-level waste regulation will require conformance with a set of minimal acceptable performance criteria while allowing flexibility in technical approaches. The body of the proposed regulation will provide the licensing requirement for managemet and disposal of low-level waste, including provisions on preparation of licensing applications, Commission actions on applications, license conditions, tests, inspections, license modifications, and enforcement. Institutional arrangements for low-level waste disposal facilities, including land ownership, facilities operation, financial liability, monitoring, decommissioning, inspection, and long-term care of waste disposal facilities will be addressed.

Appendices to the low-level waste disposal regulation will specify the technical requirements for licensing of shallow land burial and alternative disposal methods, and for disposal of wastes containing very low levels of radioactive material. Specifications regarding waste form/container performance, site selection and suitability, design and operation of sites, monitoring during and after site operations, and decommissioning will be included. An EIS will be prepared to support the regulation that will consider the environmental impacts of shallow land burial and alternative methods of low-level waste disposal.

Summary of NRC Staff Response to NRDC Ten "Allegations of Fact"

The following 10 "allegations of fact" were made by the petitioners in support of the petition for rulemaking:

1. Two of the existing commercially-operated low level waste disposal sites have experienced migration of radionuclides away from burial trenches, less than 15 years after wastes were buried.
2. Evidence from one commercial disposal site suggests that plutonium has migrated from the burial site to surrounding areas
3. The six existing burial sites were selected without adequate study of the geological, hydrological, topographical, and meteorological conditions of the areas in which the sites were located.
4. Environmental monitoring programs at several existing waste disposal sites are seriously inadequate.
5. Improper practices at existing burial sites have been corrected only extremely slowly and sometimes not at all.
6. A radioactive liquids storage tank at one disposal site has already been the subject of sabotage or vandalism.
7. Plans and funding arrangements for long-term surveillance of the disposal sites are grossly inadequate at several of the existing commercial burial grounds.
8. No site selection criteria or other standards governing the operation of low level waste burial grounds currently exist.
9. The U.S. Energy Research and Development Administration (ERDA) [2] which operates burial grounds for the low level radioactive waste generated by the Federal Government has prohibited the burial of waste contaminated by transuranic elements. ERDA currently requires storage of such waste so that it can be retrieved within 20 years.
10. The Atomic Energy Commission proposed regulations prohibiting the burial of transuranic-contaminated waste at commercial burial grounds in September 1974, but never made these regulations final.

The detailed NRC staff response to each of these 10 allegations is available for public inspection in the Commission's Public Document Room (1717 H Street NW, Washington, D.C. 20555). The staff response notes that six of the 10 "allegations of fact" (Numbers 1, 3, 4, 5, 7 and 8) made by the petitioner specifically reference a report to Congress by the Comptroller General of the United States ("Improvements Needed in the Land Disposal of Radioactive Wastes—A Problem of Centuries," General Accounting Office (GAO), January 12, 1976). NRC staff responded to the findings and recommendations of this GAO report by letter to the Comptroller General dated April 2, 1976. Many of the issues raised in the petition, allegations, and GAO report were also covered in some detail in the NRC Task Force Report NUREG–0217, and were used as input for development of the NRC low level radioactive waste management program which was published as NUREG–0240.

The staff response notes that although there have been occurrences where sites have contributed radioactivity to the local environment, at no sites have these occurrences constituted a threat to the public health and safety. The occurrences, however, have indicated a need for more specific criteria and standards for management and disposal of low level waste. A number of studies are ongoing by NRC, USGS, EPA, DOE, and State agencies to more completely assess the geohydrological characteristics of the burial sites. These studies as well as a number of other studies are being factored into NRC development of a comprehensive regulation, 10 CFR Part 61, governing the management and disposal of low level waste. Included in this regulation will be specific requirements on waste form; disposal facility siting, design and operation; monitoring; and site closure, funding and long term care. NRC's Division of Waste Management, Office of Nuclear Material Safety and Safeguards, has prepared a technical position on requirements for site closure and stabilization. This technical position is being incorporated into the licenses for the three disposal facilities currently open. Additional technical positions are planned covering other aspects of low level waste disposal operations.

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[1] Further refinements to this basic concept regarding radioactive wastes and disposal methods are being addressed in the study.

The response also acknowledges that (1) ERDA (now DOE) has an ongoing policy whereby TRU wastes are retrievably stored, and (2) the AEC in 1974 proposed a rule prohibiting burial of commercially-generated TRU waste but never made this rule final. As discussed in the response, NRC plans to replace this proposed 1974 TRU rule with a proposed waste classification regulation used to determine the types of wastes—including but not limited to TRU wastes—that can be disposed of by different methods.

Today, the only commercial disposal site still accepting small quantities of TRU waste for shallow land burial is the site located in the center of the Hanford Reservation near Richland, Washington. No public health and safety problems have been identified with the operation of the commercial site. Disposal of plutonium waste is under independent review by the NRC staff as part of their review of a renewal application for disposal of SNM waste at the site

48 FR 16499
Published 4/18/83

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10 CFR Part 20

[Docket No. PRM-20-13]

Victor E. Anderson; Withdrawal of Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Withdrawal of petition for rulemaking (PRM-20-13) that was filed by Victor E. Anderson.

SUMMARY: The Nuclear Regulatory Commission is withdrawing, at the petitioner's request, a petition for rulemaking (PRM-20-13) that was filed by Victor E. Anderson. The petitioner, in his January 17, 1979 letter, requested that the Commission amend 10 CFR Part 20 to require that health physics personnel be certified by the Commission.

ADDRESSES: A copy of the NRC's letter confirming the withdrawal of the petition is available for public inspection in the Commission's Public Document Room, 1717 H Street NW., Washington, DC. A copy of the NRC's letter confirming the withdrawal of the petition may be obtained by writing to the Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

FOR FURTHER INFORMATION CONTACT: John Philips, Chief, Rules and Procedures Branch, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: 301-492-7086 or Toll Free: 800-368-5642.

SUPPLEMENTARY INFORMATION: In a Federal Register notice published on February 28, 1979 (44 FR 11284), the Commission announced the receipt of and requested comments on a petition for rulemaking (PRM-20-13) filed by Victor E. Anderson. The comment period was subsequently extended for an additional 30 days on May 2, 1979 (44 FR 25716). The petition, which was dated January 17, 1979, requested that the Commission amend 10 CFR Part 20 to require that health physics personnel be certified by the Commission. The petitioner's proposed amendment of § 20.600 provided for the certification of health physicists on five levels. It also provided for the certification, validation, and revocation of certificates. By letter dated March 8, 1983, the NRC has confirmed that the petitioner stated his intention to withdraw his petition during a March 4, 1983 telephone conversation with a member of the NRC's staff. This withdrawal was based on the fact that several developments in radiation protection during the past few years were likely to achieve the objectives of the petition. The developments included the publication of draft NUREG-0761, revision 4 of Regulatory Guide 8.8, publication of the RSO Qualifications guide, the NRC Health Physics Appraisal program, and the INPO/Industry effort in dose reduction.

Dated at Bethesda, Md., this 6th day of April 1983.

For the Nuclear Regulatory Commission.

William J. Dircks,

Executive Director for Operations.

≫48 FR 43051
Published 9/21/83

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10 CFR Parts 20, 30, 40, and 70

[Docket No. PRM-30-58]

National Bureau of Standards, Department of Commerce; Withdrawal of a Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking: withdrawal.

SUMMARY: The Nuclear Regulatory Commission is announcing the withdrawal of a petition for rulemaking (PRM-30-58) filed by the National Bureau of Standards, U.S. Department of Commerce. The petitioner withdrew the petition in a letter dated July 25, 1983. This action is necessary to inform the public of the disposition of PRM-30-58.

ADDRESSES: A copy of the petitioner's letter of withdrawal is available for public inspection in the NRC Public Document Room, 1717 H Street NW., Washington, D.C. A copy of the letter of withdrawal may be obtained by writing the Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

FOR FURTHER INFORMATION CONTACT: Dr. Anthony Tse, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (301) 443-7902.

SUPPLEMENTARY INFORMATION: On May 14, 1981 the Nuclear Regulatory Commission received a petition for rulemaking from the National Bureau of Standards, U.S. Department of Commerce (PRM-30-58). The petition suggested amendments to NRC regulations that would exempt radioactive materials obtained directly or indirectly from environmental sources from specific license application requirements. The National Bureau of Standards collects environmental samples from unrestricted areas around the world and uses these samples to develop environmental standards. The petitioner's concern is that users of these standards not be required to obtain an NRC license because of the radioactive materials that may be present in the samples. The NRC published a notice of receipt of the petition for rulemaking and a request for comment on July 10, 1981 (46 FR 35662).

After comparing the concentrations or activities in the environmental standards to the concentrations or activities that are exempt from NRC licensing requirements, the NRC concluded that users of environmental radioactivity standards containing environmental materials need not be licensed if—

(1) The environmental materials are collected from unrestricted areas; and

(2) The National Bureau of Standards or a user of the standards does not concentrate radioactive content in the environmental materials except for the removal of moisture content during the preparation of the standards.

Based on this information, the petitioner requested that PRM-30-58 be withdrawn in a letter dated July 25, 1983.

Dated at Bethesda, Maryland this 12th day of September 1983.

For the Nuclear Regulatory Commission.

William J. Dircks,
Executive Director for Operations.

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49 FR 3667
Published 1/30/84
Comment period expires 3/30/84

10 CFR Part 20

[Docket No. PRM-20-14]

University of Utah; Filing of Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of receipt of petition for rulemaking from the University of Utah.

SUMMARY: The Commission is publishing for public comment this notice of receipt of a petition for rulemaking dated November 29, 1983, which was filed with the Commission by the University of Utah. The petition was docketed by the Commission on December 1, 1983, and has been assigned Docket No. PRM-20-14. The petitioner requests that the Commission amend its regulations to provide additional options for the disposal of very low concentrations of short-lived radionuclides.

DATE: Comment period expires March 30, 1984. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

ADDRESSES: A copy of the petition for rulemaking is available for public inspection and copying at the Commission's Public Document Room, 1717 H Street, NW., Washington, DC 20555.

All persons who desire to submit written comments concerning the petition for rulemaking should send their comments to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

FOR FURTHER INFORMATION CONTACT: John Philips, Chief, Rules and Procedures Branch, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: 301-492-7086 or Toll Free: 800-368-5642.

SUPPLEMENTARY INFORMATION: Section 20.306 of 10 CFR, published on March 11, 1981 (46 FR 16230), was designed to grant licensees greater leeway in disposing of liquid scintiallation media and animal carcasses containing tracer levels of hydrogen-3 (tritium) and carbon-14. According to the petitioner, the rule provided substantial relief from some of the financial and operational burdens of low-level radioactive waste disposal. However, the petitioner seeks further relief through additional options in order to alleviate a number of problems associated with the disposal of experimental animal waste material and certain radionuclide components, discussed below, that many licensees apparently are experiencing under the current regulations.

At present, § 20.306 addresses the disposal of hydrogen-3 and carbon-14 only. The petitioner points out that other radionuclides (i.e., phosphorus-32, sulfur-35, iron-59, iodine-125, and iodine-131(are other used in combination with hydrogen-3 and carbon-14 in medical and biological research. Further, these radionuclides have half-lives of between 8 and 87 days. Because these other radionuclides are not mentioned specifically in the regulations, some licensees currently preserve, freeze and store all animal carcasses containing radionuclides other than hydrogen-3 and carbon-14. Those licensees with authorized incinerators retain the carcasses for a short period of time prior to batch incineration. However, licensees who do not have appropriate incinerators must store wastes for a long period of time to allow the radioactivity to decay before disposing of the wastes as nonradioactive. The petitioner states that this practice of storing radionuclides prior to decay could result in risks from flammability, toxicity and infection.

Licensees must dispose of another type of radioactive waste, scintillation vials. In the past, these licensees have been accustomed to shipping intact scintillation vials in approved containers to the radioactive waste disposal site in the State of Washington, the only site accepting liquid waste. However, as the petitioner indicated, after December 31, 1983, the Washington disposal site will no longer accept unsolidified liquid scintillation media.

In order to overcome the problems that the petitioner has itemized, he has recommended the following revision and addition to the regulations:

Proposed Revision

Section 20.306 Disposal of specific wastes.

(b) 0.05 microcuries of hydrogen-3 or carbon-14, per gram of *biodegradable animal bedding material, animal excreta or* animal tissue, averaged over the weight of the entire animal; provided however, tissue may not be disposed of under this section in a manner that would permit its use either as food for humans for as animal feed.

Proposed Addition

Section 20.307 Disposal of short-lived radionuclides by burial.

Any licensee may dispose of licensed material consisting of any mixture of hydrogen-3, carbon-14 and redionuclides with half-lives of less than 100 days, in the types of waste media, at the concentration limits and to the types of burial facilities specified below:

(a) 0.05 microcuries per gram of biodegradable animal bedding material, animal excreta or animal tissue, averaged over the mass of such materials generated per animal, may be disposed of in a sanitary landfill;

(b) 0.05 microcuries per gram of medium used for liquid scintillation counting may be disposed of in an approved hazardous waste landfill without regard to the radioactivity contained in medium;

(c) Wastes that are disposed of under the provisions of this section are not be labeled as radioactive and, for purposes of collection and transport, may be treated as nonradioactive;

(d) Nothing in this section, however, relieves the licensee of maintaining records showing the receipt, transfer and disposal of such licensed material as specified in seciton 30.51 of this chapter; and

(e) Nothing in this section relieves the lciensee from complying with other applicable Federal, State and local regulations governing any other toxic or hazardous property of these materials.

According to the petitioner, these changes would substantially reduce non-radiological risk related to the collection, storage, packaging, and shipping of certain biological and chemical wastes without compromising or reducing radiation protection. It is also stated that these changes would also allow significant reductions in costs for waste disposal by NRC licensees involved in extensive biomedical research. These reduction in risk would be achieved, under these proposed amendments, in the following manner:

1. Because these wastes would be disposed of on a site that has Federal and State requirements for the control of chemical and biological hazards and that will contain waste materials for many years, the burial of radionuclides with half-lives of less than 100 days would not result in any migration into the human environment prior to

decaying into innocuous levels.

2. By limiting the wastes that can be buried under this proposal to materials that have no attraction for human contact, the risk of potential salvage of contaminated articles is eliminated.

3. The biological and chemical characteristics of the specified wastes rule out inputs to human food chains.

4. The low concentrations permitted for the proposed methods of disposal would preclude significant exposures to personnel involved in the collection and transportation of the wastes. Because of this, there would be not restrictions on handling of the waste and there would be no need for special containers or labels.

The petitioner concludes by stating that handling and disposal of the specified wastes in the manner proposed in the petition would reduce overall risk from flammable and toxic chemicals and from pathogenic organisms without significantly changing the risk from radiation exposure.

In order to help evaluate the merits of this petition, the NRC staff requests biomedical research institutions and other users of the short-lived radionuclides, in addition to their comments on the petition itself, to provide information on:

(1) Their usual inventory of these short-lived radionuclides;

(2) The amounts used and the activity, volume, and types of materials disposed of annually or monthly;

(3) Estimates of the cost of packaging, storage, transportation, and disposal of this material; and

(4) The costs of any alternative methods of disposal which have been examined. In particular, the amount of any cost savings resulting from methods of disposal which would become available if the petition were granted would be extremely helpful.

Dated at Washington, DC this 25th day of January, 1984.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

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49 FR 36653
Published 9/19/84
Comment period expires 11/19/84.

≫ **49 FR 38643**
Published 10/1/84
Correction

10 CFR Part 20

[Docket No. PRM-20-15]

Edison Electric Institute (EEI) and Utility Nuclear Waste Management Group (UNWMG); Filing of Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of receipt of petition for rulemaking from Edison Electric Institute (EEI) and Utility Nuclear Waste Management Group (UNWMG).

SUMMARY: The Commission is publishing for public comment this notice of receipt of a petition for rulemaking dated July 31, 1984, which was filed with the Commission by Michael A. Bauser on behalf of EEI and UNWMG. The petition was docketed by the Commission on July 31, 1984, and has been assigned Docket No. PRM-20-15. The petitioners request that the Commission issue a regulation governing the disposal of low-level radioactively contaminated waste oil from nuclear power plants by establishing radionuclide concentrations in waste oil at which disposal may be carried out without regard to the radioactive material content of the waste.

DATE: Submit comments by November 19, 1984. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given as to comments received on or before this date.

ADDRESSES: All persons who desire to submit written comments concerning the petition for rulemaking send their comments to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

For a copy of the petition write to the Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

The petition, copies of comments, and the accompanying document to the petition may be inspected and copied for a fee at the NRC Public Document Room, 1717 H Street NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: John Philips, Chief, Rules and Procedures Branch, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: 301-492-7086 or Toll Free: 800-368-5642.

SUPPLEMENTARY INFORMATION:

I. Background

The petitioners stated that when the Commission published its final rule creating 10 CFR Part 61 (December 27, 1982; 47 FR 57446), the Commission noted that numerous commentors had requested that it develop a "de minimis" standard which would permit certain wastes to be disposed of by less restrictive means than existing practices. At that time, the Commission expressed its agreement that establishment of such de minimis standards would reduce disposal and long-term site maintenance costs, help preserve disposal capacity for wastes with higher activity levels, enhance overall stability of disposal facilities and tend to reduce groundwater migration impacts. The Commission also expressed its willingness "to accept petitions for rulemaking . . . for declaring certain waste streams to be of no regulatory concern," and identified some of the information necessary to support such a petition.

More recently, the Advisory Committee on Reactor Safeguards (ACRS) recommended that de minimis levels or radiation exposure be established. Presently, certain criteria defining regulatory cutoff levels for radioactively contaminated waste exists in 10 CFR 20.306, which authorizes the disposal of liquid scintillation media and animal tissue containing no greater than 0.05 microcurie per gram of H-3 or C-14 without regard to their radioactivity. The petitioners stated that it was also their understanding that the draft proposed revisions to 10 CFR Part 20 defined de minimis exposure as that exposure to radiation which would present a calculated risk of biological harm so low, relative to the risks faced routinely from daily activities, that the risk from radiation would be a trifle and of no regulatory concern. The petitioners stated that they understood that a numerical dose level of one mrem was determined to represent the de minimis level of radiation exposure.

II. Waste Oil at Nuclear Power Plants

Each year, the petitioners state, quantities of waste oil containing very low levels of radioactive contamination are produced at nuclear power plants. The principal sources of the waste oil are primary system pump motors (including reactor coolant pumps) at pressurized water reactors (PWRs), and turbine and pump motors, such as recirculation and feedwater pump motors, at boiling water reactors (BWRs). Waste oil also collects in turbine and radwaste building sumps, equipment drain trays, and during maintenance operations (miscellaneous waste oils).

Radioactivity levels for sources of waste oil, such as pump turbines and motors at both PWRs and BWRs are typically in the 10^{-7} to 10^{-6}μ Ci/ml range with Mn-54, Co-58, Co-60, Cs-134 and Cs-137 the dominant radionuclides. Miscellaneous waste oils at PWRs and BWRs—from sumps, drains, etc.,—generally contain the same dominant radionuclides, but concentrations are more variable, typically ranging from 10^{-7}μ Ci/ml to 10^{-4}μ Ci/ml. These often are oil-water mixtures. Prior processing might be necessary before disposal by some of the methods addressed in the petition.

Currently, according to the petitioners, the only generally approved disposal method for low-level radioactively contaminated waste oil involves absorption or solidification, transportation to, and burial at a licensed disposal facility. Disposal of waste oil in this manner is costly, inconsistent with the NRC's policy in favor of volume reduction, and represents an inefficient use of Commission, licensee, and burial site resources.

III. Petitioners Solution to this Problem

The petitioners state that waste oil, under certain conditions, may be disposed of in a considerably more efficient manner, while providing adequate protection for both the environment and public health and safety. Data on generation rates, radionuclide concentrations and content were gathered from 15 operating plants, including 29 units (16 PWRs and 13 BWRs). A number of specific disposal methods were considered individually, as follows:

1. To burn the oil on the nuclear reactor site in a controlled location.
2. To burn the oil off site.
3. To spray it on an unpaved road, as is done for dust control.
4. To solidify it and bury it in a landfill.
5. To recycle it in the same manner as is done commercially with waste oil.

The ultimate objective was to identify mechanisms by which waste oil at specific levels of contamination could be disposed of in an efficient, environmentally acceptable, cost-beneficial manner while assuring that the postulated radiation dose does not exceed the regulatory cutoff level.

The detailed analysis which forms the basis of the petition is found in the report entitled "Development of Recommended Regulatory Cutoff Levels for Low-Level Radioactively Contaminated Oils from Nuclear Power Plants." This report was prepared for the UNWMG by OTHA, Inc., in October 1983. The report notes that it is possible to specify limiting gross activity levels for each disposal method. Specifically, waste oils can be disposed of via the six disposal methods set out in the proposed amendment.

IV. Proposed Amendment to 10 CFR Part 20

The petitioners request amendment of 10 CFR Part 20 as follows:

1. Redesignate existing paragraphs (c) and (d) and (e), respectively; and add paragraph (c) to § 220.306 to read as follows:

(c) Waste oil not exceeding the following gross activity limits by the indicated methods, provided that, the total quantity of oil disposed of at a single location by methods (1), (2), (3), and (6) either not exceed 1,000 gallons per year; or that the sum of the ratios of each radionuclide present to the concentration of that radionuclide in Part 20, Appendix E, not exceed the value of 1,000 divided by the number of gallons disposed of per year at that location, *i.e.*;

$$\sum_{i} \frac{\text{Concentration of radionuclide i}}{\text{radionuclide i Part 20, App. E concentration}} \leq \frac{1{,}000}{\text{volume of gallons disposed of at location (gal/yr)}}$$

Disposal method	Gross activity limit μCi/cm³
(1) Burn on-site, short stack	4×10^{-6}
(2) Burn on-site, tall stack	4×10^{-6}
(3) Burn off-site, short stack	4×10^{-6}
(4) Spray on road	3×10^{-6}
(5) Solidify-Bury	4×10^{-6}
(6) Recycle	6×10^{-6}

2. Add a new Appendix E to read as follows:

APPENDIX E—CONCENTRATION LIMITS FOR WASTE OIL DISPOSAL UNDER THE PROVISIONS OF 10 CFR 20.306(C) BY ELEMENT AND DISPOSAL METHOD

Nuclide	Concen. limit (pCi/cm3)	Disposal scenario
Ag110m	5.9×10^{1}	Recycle.
	2.4×10^{8}	Burn offsite-short stack.
	2.4×10^{8}	Burn onsite-short stack.
	2.9×10^{5}	Spray on road.
	2.4×10^{4}	Burn onsite-tall stack.
	7.5×10^{8}	Solidify-bury/landfill.
Ce141	1.9×10^{8}	Recycle.
	1.9×10^{4}	Burn offsite-short stack.
	9.6×10^{4}	Spray on road.
	1.9×10^{8}	Burn onsite-short stack.
	1.9×10^{8}	Burn onsite-tall stack.
	1.0×10^{13}	Solidify-bury/landfill.
Ce144	6.5×10^{4}	Burn offsite-short stack.
	8.3×10^{3}	Recycle.
	6.5×10^{5}	Burn onsite-short stack.
	1.5×10^{4}	Spray on road.

APPENDIX E—CONCENTRATION LIMITS FOR WASTE OIL DISPOSAL UNDER THE PROVISIONS OF 10 CFR 20.306(C) BY ELEMENT AND DISPOSAL METHOD—Continued

Nuclide	Concen. limit (pCi/cm3)	Disposal scenario
	8.5×10^{4}	Burn onsite-tall stack.
	2.2×10^{8}	Solidify-bury/landfill.
Co58	1.6×10^{3}	Recycle.
	2.2×10^{4}	Burn offsite-short stack.
	7.5×10^{4}	Spray on road.
	2.2×10^{4}	Burn onsite-short stack.
	2.2×10^{8}	Burn onsite-tall stack.
	1.6×10^{9}	Solidify-bury/landfill.
Co60	8.8×10^{3}	Burn offsite-short stack.
	6.3×10^{1}	Recycle.
	1.6×10^{2}	Solidify-bury/landfill.
	3.9×10^{8}	Burn onsite-short stack.
	3.1×10^{3}	Spray on road.
	3.9×10^{3}	Burn onsite-tall stack.
Cr51	4.9×10^{9}	Recycle.
	1.8×10^{5}	Burn offsite-short stack.
	2.4×10^{8}	Spray on road.
	1.8×10^{8}	Burn onsite-short stack.
	1.8×10^{7}	Burn onsite-tall stack.
	1.0×10^{13}	Solidify-bury/landfill.
Cs134	8.9×10^{1}	Recycle.
	1.2×10^{8}	Burn offsite-short stack.
	1.2×10^{8}	Burn onsite-short stack.
	1.7×10^{8}	Solidify-bury/landfill.
	4.4×10^{3}	Spray on road.
	1.2×10^{4}	Burn onsite-tall stack.
Cs137	8.1×10^{1}	Burn offsite-short stack.
	2.1×10^{3}	Solidify-bury/landfill.
	2.5×10^{3}	Recycle.
	8.1×10^{4}	Burn onsite-short stack.
	8.1×10^{3}	Burn onsite-tall stack.
	1.3×10^{4}	Spray on road.
Fe55	2.6×10^{4}	Burn offsite-short stack.

APPENDIX E—CONCENTRATION LIMITS FOR WASTE OIL DISPOSAL UNDER THE PROVISIONS OF 10 CFR 20.306(C) BY ELEMENT AND DISPOSAL METHOD—Continued

Nuclide	Concen. limit (pCi/cm3)	Disposal scenario
	2.6×10^{4}	Burn onsite-short stack.
	1.6×10^{9}	Solidify-bury/landfill.
	2.3×10^{4}	Spray on road.
	2.6×10^{4}	Burn onsite-tall stack.
	1.0×10^{14}	Recycle.
Fe59	1.3×10^{3}	Recycle.
	3.0×10^{4}	Burn offsite-short stack.
	6.6×10^{5}	Spray on road.
	3.0×10^{4}	Burn onsite-short stack.
	3.0×10^{4}	Burn onsite-tall stack.
	3.7×10^{11}	Solidify-bury/landfill.
Mn54	1.8×10^{3}	Recycle.
	6.2×10^{3}	Burn offsite-short stack.
	6.2×10^{8}	Burn onsite-short stack.
	9.1×10^{3}	Spray on road.
	6.2×10^{4}	Burn onsite-tall stack.
	5.2×10^{4}	Solidify-bury/landfill.
Nb95	2.1×10^{8}	Recycle.
	6.1×10^{8}	Burn offsite-short stack.
	1.8×10^{4}	Spray on road.
	6.1×10^{4}	Burn onsite-short stack.
	6.1×10^{6}	Burn onsite-tall stack.
	1.0×10^{13}	Solidify-bury/landfill.
Ni63	8.5×10^{2}	Solidify-bury/landfill.
	2.1×10^{4}	Burn offsite-short stack.
	2.1×10^{8}	Burn onsite-short stack.
	2.0×10^{9}	Spray on road.
	2.1×10^{4}	Burn onsite-tall stack.
	1.0×10^{13}	Recycle.
Pr143	2.8×10^{4}	Burn offsite-short stack.
	2.6×10^{4}	Burn onsite-short stack.
	2.6×10^{6}	Burn onsite-tall stack.
	1.3×10^{7}	Spray on road.
	1.0×10^{10}	Recycle.
	1.0×10^{13}	Solidify-bury/landfill.
Te127	1.1×10^{4}	Recycle.
	4.2×10^{9}	Burn offsite-short stack.
	5.3×10^{6}	Spray on road.
	4.2×10^{7}	Burn onsite-short stack.
	4.2×10^{8}	Burn onsite-tall stack.
Rb86	1.7×10^{2}	Recycle.
	6.8×10^{3}	Burn offsite-short stack.
	8.4×10^{4}	Spray on road.
	6.8×10^{4}	Burn onsite-short stack.
	6.8×10^{4}	Burn onsite-tall stack.
	1.0×10^{13}	Solidify-bury/landfill.
Te127m	1.7×10^{3}	Burn offsite-short stack.
	1.7×10^{4}	Burn onsite-short stack.
	1.7×10^{5}	Burn onsite-tall stack.
	9.7×10^{6}	Recycle.
	1.8×10^{4}	Spray on road.
	2.3×10^{7}	Solidify-bury/landfill.
Te139	1.5×10^{3}	Recycle.
	7.4×10^{4}	Spray on road.
	1.3×10^{7}	Burn offsite-short stack.
	1.3×10^{8}	Burn onsite-short stack.
	1.3×10^{9}	Burn onsite-tall stack.
Te29m	1.4×10^{3}	Recycle.
	3.8×10^{3}	Burn offsite-short stack.
	3.8×10^{4}	Burn onsite-short stack.
	6.8×10^{4}	Spray on road.
	3.8×10^{6}	Burn onsite-tall stack.
	1.0×10^{13}	Solidify-bury/landfill.
Ru103	3.0×10^{3}	Recycle.
	7.6×10^{3}	Burn offsite-short stack.
	1.5×10^{4}	Spray on road.
	7.6×10^{4}	Burn onsite-short stack.
	7.6×10^{5}	Burn onsite-tall stack.
	1.0×10^{13}	Solidify-bury/landfill.
Ru106	6.9×10^{2}	Burn offsite-short stack.
	7.1×10^{3}	Recycle.
	5.9×10^{3}	Burn onsite-short stack.
	1.4×10^{4}	Spray on road.
	5.9×10^{4}	Burn onsite-tall stack.
	4.7×10^{4}	Solidify-bury/landfill.
Sr89	3.1×10^{3}	Burn offsite-short stack.
	3.1×10^{4}	Burn onsite-short stack.
	4.9×10^{8}	Spray on road.
	1.9×10^{6}	Recycle.
	2.1×10^{6}	Burn onsite-tall stack.
	2.9×10^{10}	Solidify-bury/landfill.
Sr90	3.8×10^{1}	Solidify-bury/landfill.
	7.1×10^{1}	Burn offsite-short stack.
	7.1×10^{2}	Burn onsite-short stack.
	4.1×10^{8}	Spray on road.
	7.1×10^{3}	Burn onsite-tall stack.

APPENDIX E—CONCENTRATION LIMITS FOR WASTE OIL DISPOSAL UNDER THE PROVISIONS OF 10 CFR 20.306(C) BY ELEMENT AND DISPOSAL METHOD—Continued

Nuclide	Concen. limit (pCi/cm3)	Disposal scenario
	$1.0x10^{11}$	Recycle.
Y91	$2.9x10^{8}$	Burn offsite-short stack.
	$2.9x10^{4}$	Burn onsite-short stack.
	$4.4x10^{4}$	Recycle.
	$2.9x10^{5}$	Burn onsite-tall stack.
	$4.4x10^{9}$	Spray on road.
	$6.2x10^{9}$	Solidify-bury/landfill.
Zn65	$2.7x10^{3}$	Recycle.
	$1.0x10^{8}$	Burn offsite-short stack.
	$1.0x10^{4}$	Burn onsite-short stack.
	$1.3x10^{4}$	Spray on road.
	$1.0x10^{5}$	Burn onsite-tall stack.
	$5.8x10^{4}$	Solidify-bury/landfill.
Zr95	$2.1x10^{8}$	Recycle.
	$3.4x10^{8}$	Burn offsite-short stack.
	$1.1x10^{4}$	Spray on road.
	$3.4x10^{4}$	Burn onsite-short stack.
	$3.4x10^{5}$	Burn onsite-tall stack.
	$4.0x10^{9}$	Solidify-bury/landfill.

The petitioners conclude that both the Commission and the ACRS have expressed support for the development of regulatory cutoff levels. The Commission, in particular, the petitioners note, has invited petitions for rulemaking of particular waste streams which might be considered below regulatory concern, and has formulated some criteria identifying exposure levels deemed de minimis, and certainly below regulatory concern.

Waste oil generated in nuclear power plants, the petitioners state, appears to be particularly suitable for such treatment, because current methods of disposal are unnecessarily costly, inconsistent with NRC policy favoring volume reduction, and represent an inefficient use of NRC, licensee, and burial site resources. The petitioners conclude that the 1 mrem/year standard is a conservative value which is consistent with current NRC policy.

Dated at Washington, DC, this 12th day of September 1984.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

UNITED STATES NUCLEAR REGULATORY COMMISSION

RULES and REGULATIONS

TITLE 10, CHAPTER 1, CODE OF FEDERAL REGULATIONS—ENERGY

PART 20

STANDARDS FOR PROTECTION AGAINST RADIATION

STATEMENTS OF CONSIDERATION

25 FR 10914
Published 11/17/60
Effective 1/1/61

Statement of considerations. The Atomic Energy Commission's regulation 10 CFR Part 20 is hereby republished for the purpose of incorporating into one document all amendments to the regulation to date, including the amendment published in the FEDERAL REGISTER on September 7, 1960, to become effective January 1, 1961.

25 FR 13952
Published 12/30/60
Effective 1/1/61

On September 7, 1960 the Commission published in the FEDERAL REGISTER amendments to 10 CFR Part 20 to become effective January 1, 1961. The amendments were designed to bring the Commission's radiation protection standards into accord with the most recent recommendations of the Federal Radiation Council and the National Committee on Radiation Protection and Measurements. Subsequent to publication of the amendments on September 7, 1960, the Commission has received several comments from interested parties requesting clarification and corrections of certain sections of the regulation. The following amendments are designed to clarify and correct the regulation in the following respects:

1. Section 20.3(a)(4) of the regulation permits licensees to determine calendar quarters either (1) as successive 3-month calendar periods starting on January 1 of a year or (2) as successive periods of 13 complete consecutive weeks starting with the first complete calendar week of the year. Film badge processors have indicated that method (1) of determining calendar quarters would present problems to the industry in that every user of film badges on a monthly basis would be required to start his use on the first day of each month, thereby resulting a large influx of badges to be processed at that time of the month with only a few badges during the balance of the month. They have indicated that method (2) of determining calendar quarters is also unsatisfactory in that users of film badges on a two-week calendar basis could not keep records for a 13-week calendar quarter. Since the purpose of the regulation in defining a calendar quarter is limited to assuring that the exposure of individuals during a period of approximately 3 months is restricted to specified amounts, § 20.3(a)(4)(i) is amended to permit 3-month "calendar quarters" to start on any date within January, April, July or October rather than only on the first of the month; and to permit "calendar quarters" determined on a weekly basis to consist of alternating 14-week and 12-week periods, rather than only 13-week periods.

2. Section 20.206(c) requires Form AEC-3, (Notice to Employees), to be posted in every establishment where licensed activities are carried on regardless of whether any restricted areas which require radiation protection control measures exist in such establishment. Some licensees have pointed out that this requirement is unduly burdensome since posting of a Notice in unrestricted areas will result in many employees not working in restricted areas, nor even engaged in work with licensed material, becoming needlessly concerned as to the applicability of the poster to their activities. Since the purpose of the Notice is soley to assure that an employee working in or frequenting a restricted areas would be made aware of the information contained in the poster, § 20.206(c) is amended to require posting in such locations as to assure that employees working in or frequenting restricted areas will observe the Notice on the way to or from work.

3. Section 20.3(a)(14) of the regulation defines "Restricted area" in part as any area access to which is controlled by the licensee. Some licensees have requested clarification of the definition since access is controlled to many areas which have no relation to radioactive material. The definition has been changed by adding the phrase "for purposes of protection of individuals from exposure to radiation and radioactive materials". A corresponding change has been made in the definition of an unrestricted area in § 20.3(a)(17).

4. The Appendix "B" note in the regulation specifies methods of general applicability for determining limits for concentrations where there is a mixture in air or water of more than one radionuclide. It was not contemplated that these methods would necessarily apply in determining concentration limits for unique complex mixtures such as uranium ore dust. The concentration limit for the mixture of radionuclides in uranium ore dust calculated in accordance with these methods is lower by a factor of about 4 than previous concentration limits used for uranium ore dust. The uranium mill licensees have questioned the applicability of the Appendix "B" note methods for deriving a limit for uranium ore dust. The reduction in the limit for uranium ore dust is due to the fractional contribution of the unusually low limit for the radionuclide Thorium-230. The limit for Thorium-230 is based on a retention half-time in the lung of 4 years for pure thorium compounds. However, Thorium-230 does not appear in uranium ore dust as pure thorium compounds. The radionuclides in uranium ore dust of major health concern consist primarily of particles of insoluble uranium, which account for about 99.99 percent of the radionuclides with respect to mass, in secular equilibrium with the daughter products Thorium-230 and Radium-226 which are probably interspersed in a matrix within the uranium particle. Because of the unique physical and chemical state of the mixture of radionuclides in uranium ore dust, it does not appear appropriate to use the retention time for pure Thorium-230 as the basis for establishing a limit for ore dust. Rather, it appears desirable to use a single retention time for the mixture based upon the characteristics of the dust particle in which the radionuclides are fixed in insoluble form.

According, Appendix "B" note has been modified by adding paragraph 4 to establish concentration limits which are specifically applicable to uranium ore dust in air. It is assumed in deriving the new limits that the retention half-life of the individual radionuclides are governed not by their individual characteristics in the pure chemical state but by the characteristics of the dust particles in which the radionuclides are contained. For this purpose, a half-life of 120 days is used. This follows the practice of the International Commission on Radiological Protection and the National Committee on Radiation Protection in using a 120 day half life for all insoluble materials in the lung except thorium and plutonium. This problem is under study by the Commission and by the Federal Radiation Council and the limits specified should be considered interim values pending the result of such studies. Appropriate revisions will be made in the limits if the studies indicate a need therefor.

Inasmuch as these amendments are intended to relieve from rather than to impose restrictions under regulations currently in effect and will not adversely affect the public health and safety, the Commission has found that general notice of proposed rule-making and public procedure thereon are unnecessary and good cause exists why these amendments should be made effective as of January 1, 1961, the effective date of previously published amendments to Part 20.

Notice is hereby given that effective January 1, 1961, Part 20, Title 10, Code of Federal Regulations, "Standards for Protection Against Radiation," as amended on September 7, 1960 (25 F.R. 8595) is further amended in the following respects:

26 FR 352

Published 1/18/61

Effective 2/17/61

On February 4, 1960, the Commission issued for public comment a proposed amendment to 10 CFR Part 20 designed to prohibit issuance of licenses which would authorize the disposal of radioactive waste material on privately owned sites by persons engaged in commercial radioactive waste disposal activities. The comments received by the Commission with respect to the proposed amendment have been considered by the Commission and are on file in the Commission's Public Document Room. The only changes which have been made in the proposed amendment as published in the FEDERAL REGISTER are that the amended section has been changed from 20.304 to 20.302 and that the words "Federal or State governments" have been changed to read "Federal government or by a State government."

Pursuant to the Administrative Procedure Act, notice is hereby given that the following amendment to Title 10, Chapter I, Part 20, "Standards for Protection Against Radiation," is adopted to be effective 30 days after publication in the FEDERAL REGISTER.

26 FR 11046

Published 11/25/61

Effective 12/24/61

On pages 7142 and 7143 of the FEDERAL REGISTER of August 9, 1961 there was published a notice of proposed rule making to amend 10 CFR 20, "Standards for Protection Against Radiation" which would amend the Note to Appendix "B" of Part 20 to provide an additional standard for deriving a concentration limit for any mixture of radionuclides (1) where the identity of each radionuclide in the mixture is known but the concentration of each radionuclide in the mixture is not known, or (2) where the identity of each radionuclide in the mixture is not known but where it can be demonstrated by assay or by the process of elimination that radionuclides other than those presently specified in the Note are not present.

The amendment also specifies criteria for determining conditions under which radionuclides may be considered as not present in a mixture.

Interested persons were given 60 days in which to submit written comments in connection with the proposed amendments. No objections or suggested changes to the proposed amendment have been received by the Commission.

Pursuant to the Atomic Energy Act of 1954, as amended, and the Administrative Procedure Act of 1946, the proposed amendments of 10 CFR Part 20 are adopted, without change, as a document subject to codification.

27 FR 5905

Published 6/22/62

Effective 6/22/62

These amendments to Parts 1, 20 and 31 of the Commission's regulations are designed to reflect recent changes in the organization of the Division of Compliance, establishing five Regional Compliance Offices. In view of these organizational changes, the Compliance Field Offices listed in 10 CFR 1.6(c) and the location of field compliance staffs listed in 10 CFR 1.101(c) are no longer correct. These amendments would correct 10 CFR 1.6(c) and 10 CFR 1.101(c) to show the current location of the Regional Compliance Offices.

Appendix "D" of 10 CFR 20 presently lists the locations of the United States Atomic Energy Commission Operations Offices, and a number of sections of Part 20 and Part 31 require that certain reports be submitted to the nearest Operations Office. These amendments change Appendix "D" by listing addresses of the Regional Compliance Offices rather than the Operations Offices. Appropriate changes are made also in other sections of Parts 31 and 20 which refer to Appendix "D". Concurrently with publication of these amendments, appropriate revisions of Form AEC–3, "Notice to Employees," are being made to list the addresses of the Regional Compliance Offices.

The definition of "source material" in Part 20 is amended to bring it into conformity with the definition of "source material" in Part 40.

Because these amendments relate solely to agency organization and correction, the Commission has found that notice of proposed rule making and public procedure thereon are unnecessary and that good cause exists to make the amendments effective upon publication in the FEDERAL REGISTER.

Accordingly, pursuant to the Atomic Energy Act of 1954, as amended, and the Administrative Procedure Act of 1946, the following amendments of Parts 1, 20, and 31 of Commission regulations are published as documents subject to codification, effective upon publication in the FEDERAL REGISTER.

28 FR 6822

Published 7/3/63

Effective 9/1/63

See Part 9 Statements of Consideration.

29 FR 14434

Published 10/21/64

Effective 11/20/64

On September 17, 1963, the Commission published for public comment a proposed amendment of 10 CFR Part 20, which would revise § 20.106 and would revise Appendix "B" to Part 20 with respect to limits on release of certain radioactive material into air or water in unrestricted areas.

The Statement of Considerations published in the FEDERAL REGISTER of September 17, 1963 (28 F.R. 10170) set forth a detailed discussion of the background and basis for the proposed amendment.

The amendment implements the recommendations of the September 18, 1961, Federal Radiation Council Memorandum for the President as they pertain to the release of effluent containing radioactive material from AEC-licensed activities in the following ways:

a. It would incorporate into Part 20 revised concentration limits based on FRC recommendations, for radium 226, iodine 131, strontium 89, strontium 90 that would govern the release by licensees of these radionuclides into unrestricted areas. The limits for radium 226, and strontium 90 are less restrictive by a factor of 3. The limits for strontium 89 in air and water and for iodine 131 in air are more restrictive by a factor of 3, and the limit for iodine 131 in water is more restrictive by a factor of 7, than the present Part 20 limits.

b. It would add to § 20.106 a provision relating to limitations on the gross quantity of radioactive material released from a licensed activity in specified periods of time that will in specific circumstances be in addition to and concurrent with limitations on concentrations.

c. It would amend § 20.106 to require more specific information in support of applications for authority to release concentrations of radioactive material in effluents which exceed Part 20, Appendix "B" Table II limits.

d. It would amend criteria for approval of proposed limits higher than the Part 20 Appendix "B" limits to require the applicant to demonstrate that he has taken reasonable steps to minimize the radioactivity discharged in the effluent streams.

The amendment published below is essentially as set forth in the proposed rule, although several minor revisions have been made for clarity and completeness. This revision reflects Commission consideration of the comments and suggestions received in response to the notice of proposed rule making.

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A number of language changes have been made, proposed paragraphs (b) and (c) have been combined, and the subsequent paragraphs have been relettered.

Paragraph 20.106(c) has been modified to implement § 20.106(b) by stating that an application for higher concentration limits shall make the demonstrations required by § 20.106(b).

The second sentence of § 20.106(d) has been modified to eliminate any implication that determination of the concentration discharged through a conduit must be made by measurement at the point of discharge. The modified language would allow concentrations at the point at which material leaves a conduit to be determined from measurement at other points along the conduit or from other known data. If the concentration at the end of a conduit through which radioactive material is discharged is determined to be within the limits specified in § 20.106(a), the licensee has complied with the limits on concentrations of radioactive material in effluents to unrestricted areas. This provision is consistent with § 20.106(c) of the presently effective regulation.

The Commission is also amending § 20.305, *Treatment or disposal by incineration*, to refer to the appropriate paragraph, (b), in the revised § 20.106.

The concentration limits for the other isotopes of iodine listed in Appendix "B", Table II, 10 CFR Part 20, have been revised to make them consistent with the intake guides recommended by the FRC for iodine 131, taking into account the effective half-life and absorbed radiation energy of the individual iodine radionuclides.

Pursuant to the Atomic Energy Act of 1954, as amended, and the Administrative Procedure Act of 1946, the following amendment of Title 10, Chapter I, Part 20, "Standards for Protection Against Radiation", is published as a document subject to codification to be effective thirty (30) days after publication in the Federal Register.

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29 FR 14661
Published 10/28/64

In F.R. Doc. 64–10683, appearing at page 14434 of the issue for Wednesday, October 21, 1964, the following correction is made: In the eighth line of the amendatory language of item 2, "$I^{132}S$" should read "$I^{134}S$".

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30 FR 15801
Published 12/22/65
Effective 1/21/66

Radioactivity Concentrations in Air and Water

On August 10, 1965, the Commission published in the Federal Register (30 F.R. 9953), a proposed amendment of its regulation, "Standards for Protection Against Radiation," 10 CFR Part 20, which would (1) provide values for certain individual radionuclides not presently listed in Appendix B, (2) provide values generally applicable to radionuclides not individually listed, (3) revise existing values for occupational exposure to soluble strontium-90, and (4) modify the footnotes and the note following Appendix B to make them consistent with other changes in the Appendix.

All interested persons were invited to submit written comments and suggestions for consideration in connection with the proposed amendment within 60 days after publication of the notice in the Federal Register.

Upon consideration of the comment received, and other factors involved, the Commission has concluded that the proposed amendment, with two minor changes, should be published as an effective rule. Except for these changes, namely the addition of concentration values for xenon-133m, and the deletion of the last line of note 3.c., the text of the amendment set out below is identical with the text of the proposed amendment published August 10, 1965.

Pursuant to the Atomic Energy Act of 1954, as amended, and the Administrative Procedure Act of 1946, the following amendment of Title 10, Chapter I, Part 20, Code of Federal Regulations, is published as a document subject to codification, to be effective thirty (30) days after publication in the Federal Register.

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31 FR 86
Published 1/5/66

Radioactivity Concentrations in Air and Water

Correction

In F.R. Doc. 65–13621 appearing at page 15801 in the issue for Wednesday, December 22, 1965, the fifth paragraph of the first column in the table set forth in item 3 now reads: "If it is known that alpha-emitters and Sr 90, I 129, Pb 210, Ac 227, Ra 228, Pa 230, Pu 240, and Bk 249 are not present". It is corrected to read: "If it is known that alpha-emitters and Sr 90, I 129, Pb 210, Ac 227, Ra 228, Pa 230, Pu 241, and Bk 249 are not present".

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31 FR 10514
Published 8/5/66
Effective 11/3/66

Labeling of Containers

On October 29, 1964, the Commission published in the Federal Register (29 F.R. 14756) a proposed amendment of 10 CFR Part 20, "Standards for Protection Against Radiation," which would provide in § 20.203(f) a requirement that containers in which greater than specified quantities of licensed material are stored, used or transported must, with certain exceptions, be labeled with information as to kinds and approximate activities of the contained material and dates for which activities are specified. All interested persons were invited to submit written comments and suggestions for consideration in connection with the proposed amendment within 60 days after publication of the notice in the Federal Register. After careful consideration of the comments and other factors involved, the Commission has adopted the rule set forth below.

The amended rule requires that containers of licensed material be labeled with the radiation caution symbol and legend. The label will identify the material in the container and provide information sufficient to permit individuals using, handling or working in the vicinity of the container to take precautions to avoid or minimize exposures to radiation or to radioactive materials.

The presently effective § 20.203(f) excepts laboratory containers, such as beakers, flasks, and test tubes used transiently in laboratory procedures, from the labeling requirements when the user is present. The rule set forth below extends this exception to any container attended by an individual who takes the precautions necessary to prevent the exposure of others to radiation or radioactive materials in excess of the limits established in 10 CFR Part 20. The present amendments add exceptions for containers which are accessible only to individuals authorized to handle or use them, or to work in the vicinity thereof, provided that the contents are identified to such individuals by a readily available written record, and for manufacturing or process equipment such as nuclear reactors, reactor components, piping and tanks.

The amendment to § 20.203(f) set forth below provides an exception for containers in transport which are labeled in accordance with Interstate Commerce Commission, Federal Aviation Agency and Coast Guard regulations. An amendment to § 20.204 provides an exception from posting requirements for radioactive material packaged and labeled in accordance with Interstate Commerce Commission, Federal Aviation Agency and Coast Guard regulations. Section 20.205 is deleted.

Pursuant to the Atomic Energy Act of 1954, as amended, and the Administrative Procedure Act of 1946, the following amendments of Title 10, Chapter I, Part 20, Code of Federal Regulations, are published as a document subject to codification, to be effective 90 days after publication in the Federal Register.

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34 FR 7500
Published 5/9/69
Effective 7/8/68

Reports of Loss or Theft of Licensed Material

On October 23, 1968, the Atomic Energy Commission published in the FEDERAL REGISTER (33 F.R. 15666) for comment a proposed amendment to its regulation, "Standards for Protection Against Radiation", 10 CFR Part 20, which would establish additional requirements regarding reports of loss or theft of licensed material.

Interested persons were invited to submit written comments and suggestions for consideration in connection with the proposed amendment within 60 days after publication of the notice of proposed rule making in the FEDERAL REGISTER. After consideration of the comments and other factors involved the Commission has adopted the proposed amendment. The text of the amendment set out below is identical with the text of the proposed amendment published on October 23, 1968.

Section 20.402 of 10 CFR Part 20 presently requires licensees of the Atomic Energy Commission to report to the Commission by telephone and telegraph any loss or theft of byproduct, source, or special nuclear material immediately after its occurrence becomes known to the licensee if it appears to the licensee that a substantial hazard may result to persons in unrestricted areas. Section 20.402 does not require that the licensee submit information as to the circumstances surrounding the loss or steps taken to recover the licensed material. The telegraphic report occasionally is incomplete or even misleading since it may have been filed with the Commission before the facts were fully developed.

The amendment of 20.402 set forth below requires a licensee to file a written report in addition to the telephone and telegraph report presently required by § 20.402. The written report must be filed within 30 days from the date that the licensee learns of the loss or theft and would include the following information: Description of the licensed material including kind, quantity, chemical, and physical form; conditions under which loss or theft occurred; disposition or probable disposition of the radioactive material; known radiation exposures and circumstances under which they occurred; extent of possible hazard to persons in unrestricted areas; and steps which have been taken or will be taken to recover the material and to prevent a recurrence of the loss or theft. The amendment provides also that any report filed with the Commission pursuant to § 20.402 shall be so prepared that names of individuals who have received exposure to radiation are stated in a separate part of the report.

Subsequent to filing the written report the licensee would be required to report any substantive additional information which becomes available on the loss or theft within 30 days after he learns of such information.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendment of Title 10, Chapter I, Code of Federal Regulations, Part 20, is published as a document subject to codification effective sixty (60) days after publication in the FEDERAL REGISTER.

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35 FR 5033
Published 3/25/70
Effective 4/24/70

High Radiation Areas

On September 25, 1969, the Atomic Energy Commission published in the FEDERAL REGISTER (34F.R. 14766) proposed amendments to § 20.203(c), 10 CFR Part 20, of its regulations, regarding the control of access to high radiation areas.

The proposed amendments would : (a) Provide for an additional method of controlling access to high radiation areas by locking access points, with positive control over each individual entry; (b) require–that controls over access to high radiation areas be established in such a way that no individual will be prevented from leaving a high radiation area; (c) require control of access to high radiation areas established for a period of 30 days or less and provide that direct surveillance to prevent unauthorized entry may, in such cases, be substituted for control devices or locks; and (d) provide that an applicant may apply to the Commission for approval of methods not included in the regulation for controlling access to high radiation areas.

Interested persons were invited to submit written comments and suggestions for consideration in connection with the proposed amendment within 60 days after publication of the notice of proposed rule making in the FEDERAL REGISTER. After consderation of the comments received and other factors involved, the Commission has decided to adopt the proposed amendment with the following minor modifications to § 20.204.

Section 20.204(d), 10 CFR Part 20, has been amended to provide that control is not required for each entrance or access point to a room or other area which is a high radiation area solely because of the presence of licensed material prepared for transport and packaged and labeled in accordance with regulations of the Department of Transportation. Similarly, § 20.204(b), 10 CFR Part 20, has been amended to provide that control is not required for each entrance or access point to a room or other area in a hospital which is a high radiation area because of the presence of patients containing byproduct material: *Provided,* That there are personnel in attendance who will take the precautions necessary to prevent the exposure of any individual to radiation in excess of the limits established in the regulations of this part.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 20, are published as a document subject to codification effective thirty (30) days after publication in the FEDERAL REGISTER.

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35 FR 6425
Published 4/22/70
Effective 5/22/70

On August 10, 1968, The Atomic Energy Commission published in the FEDERAL REGISTER (33 F.R. 11414) proposed amendments to Parts 30, 31, 32, and 35 of its regulations. The proposed amendments would (a) exempt from licensing small quantities of byproduct material; (b) revoke the existing general license set out in § 31.4 for similar quantities of byproduct material; (c) establish requirements in Part 32 for the issuance of specific licenses for distribution of exempt quantities of byproduct material; and (d) clarify wording in Part 35 that exempt quantities of byproduct material are not to be used in humans.

On the same date, the Commission published (33 F.R. 11413) proposed amendments to Appendix C of Part 20 of its regulations. Appendix C currently consists of a list of radioisotopes in which the kinds and quantities of byproduct material are identical to those generally licensed "not as a scaled source" by § § 31.4 and 31.100, Schedule A, 10 CFR Part 31. The list of quantities in Appendix C, 10 CFR Part 20, is referred to in providing exceptions from labeling requirements pursuant to § 20.203 and in specifying quantities of byproduct material which may be disposed by release into santitary sewerage systems pursuant to § 20.303(b) (2) or by burial in soil pursuant to § 20.304.

The proposed amendments to Part 20 would conform the microcurie amounts of byproduct material listed in Appendix C, 10 CFR Part 20, with the quantities proposed for exemption in the new § 30.71, Schedule B, 10 CFR Part 30. Americium-241, while not included in § 30.71, Schedule B, would be added to Appendix C, Part 20, and the quantities listed in Appendix C for radium-226, uranium-233, uranium-234, uranium-235, and plutonium-239 would be reduced to values more consistent with the toxicity of those nuclides and the criterial used to derive the exempt quantities. The quantities listed for natural uranium and natural thorium would not be reduced because of the low specific activity of those source materials and the attendant low risk of human intake of the materials. The last entry of Appendix C, Part 20, presently provides a quantity for "unidentified radioactive materials or any of the above in unknown mixtures." The amendment would provide two listings, one for unlisted alpha emitting radionuclides or mixtures of alpha emitters of unknown composition, and one for any radionuclides not listed in Appendix C or mixtures of beta emitters of unknown composition.

Interested persons were invited to submit written comments and suggestions for consideration in connection with the proposed amendments within 60 days after publication of the notice of proposed rule making in the FEDERAL REGISTER. After consideration of the comments received on the notices of proposed rule making and other factors involved, the Commission has adopted the proposed amendments to Part 20 with the following minor modifications: (1) The quantity of carbon-14 listed in Appendix C has been reduced from 1,000 to 100 microcuries; (2) the quantity for iodine-134 has been reduced from 100 to 10 microcuries; and (3) the quantities of carbon-14 used in the note at the end of Appendix C have also been revised to conform to the revised quantity.

Concurrent with publication of this present notice, the Commission is publishing a notice of rule making to make effective, with some minor modifications, the amendments to Parts 30, 31, 32, and 35. The above described changes in the proposed amendments to Appendix C of Part 20 have been made to conform to similar reductions in § 30.71, Schedule B, 10 CFR Part 30.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 20, are published as a document subject to codification, to be effective thirty (30) days after publication in the FEDERAL REGISTER.

36 FR 23138
Published 12/4/71
Effective 1/3/72

Disposal of Radioactive Wastes at Sea

Notice is hereby given of the amendment of the Atomic Energy Commission's regulation "Standards for Protection Against Radiation," 10 CFR Part 20.

In his April 15, 1970, message to the Congress, the President directed the Chairman of the Council on Environmental Quality (CEQ) to conduct a study regarding ocean dumping of wastes, including the dumping of radioactive wastes. The President's message asked the Council to work with other Federal agencies and with State and local governments on a comprehensive study that would result in research, legislative, and administrative recommendations. The study led to the publication of "Ocean Dumping: A National Policy, a Report to the President prepared by the Council on Environmental Quality" in October 1970.

With respect to the dumping of radioactive waste, the CEQ report made the following findings and recommendations:

> The current policy of prohibiting ocean dumping of high-level radioactive wastes should be continued. Low-level liquid discharges to the ocean from vessels and land-based nuclear facilities are, and should continue to be controlled by Federal regulations and international standards. The adequacy of such standards should be continually reviewed. Ocean dumping of other radioactive wastes should be prohibited. In a very few cases, there may be no alternative offering less harm to man or the environment. In these cases ocean disposal should be allowed only when the lack of alternatives has been demonstrated. Planning of activities which will result in production of radioactive wastes should include provisions to avoid ocean disposal.

The Atomic Energy Commission's policy since 1960 is consistent with the policy expressed in the CEQ report. The AEC has not permitted ocean disposal of high-level radioactive waste. The release of low-level liquid effluents to the ocean from vessels and land-based nuclear facilities, such as nuclear powerplants, is subject to Federal controls and continually reviewed.

In June 1960 the Commission placed a moratorium on the issuance of new licenses for sea disposal. Existing licenses authorizing sea disposal were permitted to remain in effect and licensees were permitted to continue waste disposal operations at sea. Early in 1960 the AEC also authorized licensees to use, on an interim basis, AEC land burial sites in Idaho Falls, Idaho, and Oak Ridge, Tenn. In September 1962 the first commercial land burial facility, located in Nevada, was licensed and became available for use by private organizations. Shortly thereafter, the AEC withdrew the use of the interim land burial sites by licensees. Since that time, licensed commercial land burial facilities have been established in the States of Kentucky, New York, Washington, Illinois, and South Carolina.

There has been very little interest in sea disposal in the last few years due primarily to the availability of land burial sites. At the time the moratorium became effective, there were seven commercial firms licensed by the AEC to collect radioactive waste from other persons and to dispose of the waste at sea. In addition, there were eight organizations licensed by the AEC to dispose of waste generated in their own laboratories. At present, there is one commercial organization authorized to dispose of radioactive waste at sea. This licensee is not actively engaged in sea disposal at present. Since 1965, less than 200 curies of radioactive waste have been disposed of at sea. The last disposal at sea was made in June 1970.

The Atomic Energy Commission's existing policy to phase out sea disposal which is consistent with the spirit of the CEQ report, the alternative means available for disposal of radioactive waste, and the lack of impact on the nuclear industry of discontinuance of sea disposal of radioactive waste provide the basis for the amendment to 10 CFR Part 20. The adoption of this rule change does not mean that the Commission considers sea disposal of radioactive waste an unsafe practice. Rather, it applies to licensee operations a policy which already exists for the AEC's own operations and is consistent with the CEQ's recommendations with respect to sea disposal of radioactive waste. The provisions of § 20.302 do not presently, and will not under this amendment, apply to low levels of radioactive material in liquid effluents released from nuclear facilities in accordance with other provisions of the Commission's regulations.

Under the amendment to Part 20 set forth below, the Atomic Energy Commission would consider, on a case-by-case basis, applications for disposal of radioactive waste at sea. The applicant would be required to show that sea disposal offers less harm to man or the environment than other practical alternative methods of disposal.

Since the amendment merely codifies existing policy, the Commission has found that good cause exists for omitting notice of proposed rule making and public procedure thereon as unnecessary.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendment to Title 10, Chapter I, Code of Federal Regulations, Part 20, is published as a document subject to codification, to be effective 30 days after publication in the FEDERAL REGISTER.

38 FR 22220
Published 8/17/73
Effective 9/17/73

Reports to Employees and Other Individuals

The Atomic Energy Commission published a notice in the FEDERAL REGISTER on January 4, 1973 (38 FR 805) that it had under consideration proposed amendments to 10 CFR Part 20 of the Commission's regulations. The amendments would transfer from 10 CFR Part 20 certain sections that would be incorporated in the new 10 CFR Part 19, and would add to 10 CFR Part 20 appropriate references to new 10 CFR Part 19 so that the transferred provisions could be easily found. A new section would be added containing the requirements for notification and reports to individuals which could include persons other than employees. The requirements for reports to individuals as specified in §§ 20.405(c) and 20.408 would be combined into one paragraph of the new section. Interested persons were invited to submit written comments or suggestions for consideration in connection with the proposed amendments within 45 days after publication of the notice of proposed rulemaking in the FEDERAL REGISTER.

After consideration of the comments received, the Commission has adopted the proposed amendments. Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 20 are published as a document subject to codification, to be effective on September 17, 1973.

Concurrently with publication of this notice, the Atomic Energy Commission is publishing a new part to its regulations, 10 CFR Part 19, Notices, Instructions and Reports to Workers; Inspections.

38 FR 29314
Published 10/24/73
Effective 10/24/73

Definitions of Units of Radioactivity

Units of radioactivity used in the regulations of the Atomic Energy Commission include the "curie," "millicurie," and "microcurie". Abbreviations for these terms are frequently used by licensees of the Commission in ordering radioactive materials and for other purposes. Personnel who are unfamiliar with units of radioactivity may err in translating the abbreviations, or in identifying "millicurie" as one-thousandth of a curie and "microcurie" as one-millionth of a curie.

The amendments of the Commission's regulations set out below add a definition for "millicurie" and substitute the word "microcurie" for the abbreviation of this unit where it appears in the text of § 32.17 of Part 32. In those instances where abbreviations for "curie," "millicurie," and "microcurie" are retained, such as in charts, the abbreviations are changed to "Ci," "mCi," and "μCi," as appropriate.

In normal business usage, wherever possible the appropriate unit should be written out as microcuries, millicuries, or curies, and the abbreviations μCi, MCi, or Ci should not be used.

Inasmuch as the amendments set forth below are of a minor nature, good cause exists for omitting notice of proposed rule making, and public procedure thereon, as unnecessary.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Parts 20, 30, and 32 are published as a document subject to codification.

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39 FR 17972
Published 5/22/74
Effective 5/22/74

Procedures for Picking Up, Receiving and Opening Packages

On May 18, 1973, the Atomic Energy Commission published in the FEDERAL REGISTER (38 FR 13033) proposed amendments to 10 CFR Part 20 of its regulations. The proposed amendments would require that licensees who pick up packages of radioactive material at a carrier's facility do so "as expeditiously as possible" and that all labeled packages of radio active material in other than gaseous or special form be monitored "promptly" on receipt for significant, removable, external contamination.

Interested persons were invited to submit written comments and suggestions. Many comments were received, the majority coming from members of the medical profession. Most of the comments urged a greater distinction between packages with little chance of leakage and small potential hazard even if leakage occurred, and packages with greater potential leak-hazard.

On December 23, 1973, the Atomic Energy Commission published in the FEDERAL REGISTER (38 FR 35489), a revised proposed amendment. That proposal recognized a greater distinction in the potential leak-hazard of different packages, and would have provided a number of exemptions from the package monitoring requirements for the lower potential leak-hazard packages.

As provided in the second notice of proposed rule making, a public meeting was held on January 17, 1974 to afford interested persons the opportunity to present statements and to discuss the proposed amendments with the regulatory staff. Representatives from the radiopharmaceutical industry, from Delta Airlines (the petitioner for rule making), and from the Society of Nuclear Medicine, participated in the meeting. The participants generally agreed that the amendments should include a provision that recipients of Type B packages maintain a 24-hour capability to be notified of the arrival of a package for pick up. Such a provision, together with a requirement that a Type B package recipient make arrangements for receipt of a Type B package at the time of its arrival, would provide assurance that Type B packages will be quickly transferred from the carrier to the recipient. Since it appears that recipients of Type B packages are able to be notified and to receive packages, the suggested requirements have been added to the rule without further opportunity for comment.

In view of the possibility that there may be some occasions where shipment of improperly prepared or damaged packages may have produced hazardous levels of radiation during transportation, the rule as adopted requires monitoring of packages for external radiation levels. This monitoring requirement is applicable to all packages containnig radioactive material in excess of Type A quantities, which are not transported under exclusive use conditions, where the consignee and consignor control the handling of packages. Where radiation levels are found to be in excess of limits specied in the regulations of the Department of Transportation (49 CFR Parts 170–189), the rule requires that the final delivering carrier and the AEC be notified immediately.

Ten written comments were received on the proposed rule, in addition to those offered at the public meeting. Some of the comments suggested additional exemptions from the proposed package monitoring requirement on the basis of small potential leak-hazard. These comments have, for the most part, been reflected in the amendments which follow. Some comments suggested more explicit and stringent requirements on the time periods allowed for the pick up or monitoring of packages, and other comments suggested less stringent requirements. The Commission has not found sufficient reason for modifying the proposed requirements.

Other comments suggested that pick up and monitoring of packages over weekends should not be required and that, for packages which are not removed from the carrier's vehicle for some period after delivery, monitoring be delayed until the package is unloaded from the vehicle. Others suggested that the rule apply only to packages which were damaged or showed evidence of leaking. Adoption of these suggestions would defeat a prime purpose of the amendments of promptly identifying packages which have excessive external radiation levels or leak in the absence of an accident or obvious damage, because they have not been properly assembled or closed.

One commenter maintained that the external contamination levels at which a report would have to be made were too high in comparison to acceptable levels established in the regulations of the Department of Transportation and to levels established elsewhere by AEC for unrestricted areas. The Commission agrees that the levels in this rule are not appropriate under normal working conditions, but has found them acceptable as an indicator of package leakage.

After consideration of the comments and other factors involved, the Commission has revised the proposed amendment as follows:

(1) A requirement has been added to the effect that persons who expect to receive a package containing radioactive material in excess of Type A limits make arrangements to receive the package when it is offered for delivery at his facility by the carrier, or, if the package is to be picked up by the licensee at the carrier's facility, make arrangements to receive notification from the carrier of the arrival of the package, at the time of arrival.

(2) An exemption has been added for packages containing up to 10 millicuries of tritium, carbon-14, sulfur-35, or iodine-125. These materials are extensively used in medicine and research and have a very low hazard potential even in the event of leakage. Considerable unnecessary effort and expense would be incurred if these materials were subjected to the rule.

(3) A requirement has been added that on receipt Type B packages be monitored for external radiation levels.

In summary, the amendments adopted impose the following requirements:

(1) A licensee who expects to receive a package containing quantities of radioactive material in excess of Type A limits (as detailed in the table in § 20.205(b)) must make arrangements (consistent with the manner in which he orders and receives packages of radioactive materials) to receive the package when it is offered for delivery at his facility by the carrier, or, if the package is routed to be picked up by the consignee, make arrangements to receive notification from the carrier of the arrival of the package, at the time of arrival.

(2) If the package routing requires pickup by the recipient, such packages must be expeditiously picked up from the carrier's facility upon notification. This does not require persons to pick up packages at the carrier's facility if they would not otherwise have done so.

(3) Packages containing radioactive material exceeding the quantities or in forms other than those specifically exempted in the amendment must be monitored for external contamination and packages containing more than Type A quantities must be monitored for external radiations levels as soon as practicable after receipt, within three hours if the package is received during normal working hours or within 18 hours if received outside of normal working hours.

(4) If contamination of external surfaces or radiation levels of a package above specified limits is found, the final delivering carrier and the Commission must be notified immediately.

The purpose of the amendments is to facilitate the transfer of radioactive material packages from the transportation system to the consignee, to assure that the relatively high potential radiation hazard packages are monitored for evidence of leakage or excessive external radiation levels in a reasonably short period after transportation, and that any such evidence is immediately reported to the carrier and to AEC in order that radiation exposures and spread of contamination can be minimized. A Regulatory Guide, "Procedures for Picking Up and Receiving Packages of Radioactive Material," to assist licensees in understanding and complying with the amendments has been prepared and is being made available concurrent with publication of the amendments.

In view of the fact that this amendment is intended to prevent excessive spread of contamination, as occurred in the aircraft incident in January 1972, and to make known at the earliest possible time any undue radiation exposures from the transportation of improperly packaged radioactive material as was the case in the recent aircraft incident of April 5, 1974, any delay in the implementation of the rule would be undesirable and contrary to the public interest. The Commission has therefore determined that good cause exists for making the rule effective on **May 22, 1974.** The incidents referenced here have previously been described in AEC public announcements.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendments to 10 CFR Part 20, are published as a document subject to codification.

39 FR 23990
Published 6/28/74
Effective 7/29/74

Special Curie Definitions and Concentration Values in Air and Water for Uranium and Thorium

The Atomic Energy Commission published a notice in the FEDERAL REGISTER on April 16, 1974 (39 FR 13671) that it had under consideration proposed amendments to 10 CFR Part 20 of the Commission's regulations. As proposed, the amendments would discontinue the use in 10 CFR Part 20 of the special curie definitions for natural uranium and natural thorium, and would amend associated concentration and quantity values in 10 CFR Part 20. These amendments were proposed in response to a petition for rulemaking (PRM-20-3) filed with the Commission by the General Electric Co. on October 30, 1972. In addition to these changes, the Commission also proposed a new footnote 3 to Appendix B of 10 CFR Part 20 which would provide a warning that the chemically toxic properties of uranium should be considered for certain mixtures of the naturally occurring uranium isotopes, establish 0.2 milligrams uranium per cubic meter of air as the appropriate concentration value for occupational exposure, and establish a weekly intake limit for any mixture of uranium-238, uranium-234 and uranium-235. Interested persons were invited to submit written comments or suggestions for consideration in connection with the proposed amendments within 45 days after publication of the notice of proposed rulemaking in the FEDERAL REGISTER.

After consideration of the comments received, the Commission has adopted the proposed amendments. The text of the amendments set out below is identical with the text of the proposed amendments previously published in the FEDERAL REGISTER for comment.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 20 are published as a document subject to codification.

39 FR 25463
Published 7/11/74

Special Curie Definitions and Concentration Values in Air and Water for Uranium and Thorium

Correction

In FR Doc. 74-14866 appearing at page 23990 in the issue for Friday, June 28, 1974, make the following changes:

40 FR 8774
Published 3/3/75
Effective 3/3/75

Energy Reorganization Act; Revisions to Chapter I to Reflect Organizational and Procedural Changes

See Part 2 Statements of Consideration.

40 FR 26679
Published 6/25/75
Effective 6/25/75

PART 20—STANDARDS FOR PROTECTION AGAINST RADIATION

Storage and Control of Licensed Materials

Section 20.207 of 10 CFR Part 20 requires that licensed materials stored in an unrestricted area be secured against unauthorized removal from the place of storage. The intention of the section is to assure that proper controls are maintained over licensed radioactive materials at all times.

Since the references to "storage" might not clearly convey the intention that constant control be maintained over all licensed radioactive materials in unrestricted areas, § 20.207 is being amended by the addition of clarifying wording to assure unequivocal understanding of the requirement.

Inasmuch as the amendments set forth below are of a minor nature, good cause exists for omitting notice of proposed rule making, and public procedure thereon, as unnecessary, and for making the amendments effective upon publication in the FEDERAL REGISTER.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, and sections 552 and 553 of title 5 of the United States Code, the following amendment to Title 10, Chapter I, Code of Federal Regulations, Part 20, is published as a document subject to codification.

40 FR 42557
Published 9/15/75
Effective 9/15/75

Miscellaneous Amendments to Chapter

Notice is hereby given of the amendment of the Nuclear Regulatory Commission's regulations in 10 CFR Parts 20 and 73 and revocation of 10 CFR Part 37.

The amendments correct the definition of "calendar quarter" in § 20.3(a)(4) and change certain telephone listings and other pertinent information regarding the Commission's Regional Offices in Appendix D of 10 CFR Part 20 and Appendix A of 10 CFR Part 73.

The amendments revoke 10 CFR Part 37, "Radioisotope Research Support Program." In accordance with § 37.14 the radioisotope research support program expired in 1961.

Because these amendments relate solely to corrections and minor matters, the Commission has found that good cause exists for omitting notice of proposed rule making, and public procedure thereon, as unnecessary, and for making the amendments effective on September 15, 1975.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Parts 20 and 73 and revocation of Part 37 are published as a document subject to codification.

40 FR 50704
Published 10/31/75
Effective 1/29/76

PART 20—STANDARDS FOR PROTECTION AGAINST RADIATION

An Occupational Exposure Limit for Radon-222 and Its Use When Uranium Ore Dust Is Present

On June 24, 1974, the Atomic Energy Commission published in the FEDERAL REGISTER (39 FR 22428) proposed amendments of 10 CFR Part 20 of its regulations. The main purpose of the amendments was to lower the limit on occupational exposure to airborne radon-222 and its daughters to one-third of that currently permitted. The proposed limit is in agreement with guidance to Federal agencies issued by the Environmental Protection Agency and with the recommendations of the International Commission on Radiological Protection (ICRP) and the National Council on Radiation Protection and Measurements (NCRP).

Another important purpose of the amendments was to change the uranium ore dust provision in paragraph 4 of the Note to Appendix B of Part 20. Currently, concentrations of radon-222 and its daughters need not be considered if the uranium concentration is held within the permissible limit given in paragraph 4. The proposed amendments would require consideration of radon-222 and its short-lived daughters in addition to uranium. When paragraph 4 was adopted the Atomic Energy Commission staff believed that if uranium concentrations were adequately controlled, concentrations of radon and its daughters would be far below the applicable limits. Subsequent measurements in uranium mills have shown concentrations of radon and its daughters to be higher than was expected.

Six public comments on the proposed amendments were received. None of these comments objected to its two main purposes. Two important issues were raised, however. It was questioned whether the limit on radon daughter exposure was expressed in the best way. It was also suggested that the proposed concentration value for radon daughters should have been even lower.

The proposed amendments expressed limits on radon daughters in an unconventional way—in microcuries of alpha activity of radon daughters per milliliter. This approach had the advantage of using units of microcuries per milliliter as is done for all other nuclides in Appendix B. Also it places a limit directly on radon daughters, which cause far more alpha particle exposure than the radon itself.

There are two common ways to represent radon and radon daughters limits. One is to specify a limit on radon-222 itself. If radon concentrations are held below this limit, exposure from both radon and its daughters will be within permissible levels. The other is to express a limit on daughters in terms of "working levels." (A "working level" is generally defined as any combination of short-lived radon daughters in one liter of air, without regard to the degree of equilibrium, that will result in the ultimate emission of 1.3×10^5 MeV of alpha particle energy.)

If the radon daughter concentrations are held below the limit, then exposure from both the radon and its daughters will be within permissible levels.

The Commission has decided to express its limits on exposure to radon and its daughters in both conventional ways instead of in the manner proposed in the FEDERAL REGISTER notice of June 24, 1974. Table I of Appendix B has been amended to change the radon-222 concentration to 3×10^{-8} microcuries per milliliter. This is one-third the value formerly in effect. A new footnote gives an alternate limit of one-third "working level" for radon daughters. The two values are equivalent when the daughters are in equilibrium with the radon-222. The licensee may use whichever value he prefers.

A chart in § 20.5(b) relating radon concentration to radon daughter alpha activity has been deleted. The chart is no longer necessary since measurements of radon daughter alpha activity ("working levels") are now acceptable for the purpose of Appendix B of Part 20.

A chart in the proposed amendments which gave alpha activities at several times after counting is not incorporated in the effective amendments. That chart was based on the modified Kusnetz method for determining "working levels." Instead the Commission will allow any generally acceptable measurement technique for determining "working levels." Among such acceptable techniques currently available are the Kusnetz method, the modified Kusnetz method, the Tsivoglou method, integrating alpha monitoring, and instant working level meter techniques.

The Environmental Protection Agency in its comments on the proposed rule said that the limit should be at a level "as low as practicable" for uranium mills. The NRC fully supports the "as low as practicable" concept. It is Commission policy that uranium mills, in addition to meeting the individual limits in Appendix B of Part 20, should operate in a manner consistent with that objective. However, the need for specific numerical guidance on "as low as practicable" (or "as low as reasonably achievable") is a separate matter, the further consideration of which should not delay the implementation of the present amendments. The application of the "as low as reasonably achievable" concept also does not remove the necessity for individual exposure limits in Appendix B of Part 20.

Another commentor suggested lowering the proposed radon limit by an additional factor of ten. He did not believe the proposed values contained a margin of safety. The Commission does not believe the limit on radon and its daughters need be lower than originally proposed. Extensive studies of uranium miners here and abroad have shown no statistically significant excess of lung cancers in miners receiving radon daughter exposures of 120 "working level" months or less.[1] At the limit herein adopted by the Commission it would take 30 years to get an exposure of 120 "working level" months. Among source material licensees radon is found in significant quantities only in certain parts of uranium mills where a few specific processes are carried out. Thus, although permissible, a cumulative exposure of a mill worker to 120 working level months is highly unlikely. Nevertheless, the Commission will periodically review the limit on radon as more data on mortality among workers exposed to radon become available.

Another comment was that the value in Table II (the effluent limit) should also be lowered. The Table II effluent limit for radon-222 is beyond the scope of these amendments which consider only occupational exposures. Effluent limitation standards are under study by the NRC staff.

One comment said that the ore dust limit in paragraph 4 of the Note to Appendix B is based on an incorrect premise on the behavior of thorium-230 in the lung and is therefore invalid. The question of the behavior of thorium-230 in the lung is being studied by the Commission. If it is concluded that a change in paragraph 4 of the Note to Appendix B is called for, another amendment will be proposed.

Another comment suggested annual averaging for radon-222 rather than quarterly averaging as was proposed. The reason given was that the official Environmental Protection Agency guidance gave an annual limit, and that the Commission should not be more restrictive than the officially recommended limit. The Commission agrees that limits on radon exposure may be based on an annual average.

A change was made in the ore dust limit in paragraph 4 of the Note. Its applicability was ended at radium-226 instead of extending down the decay chain to lead-210 and its daughters. While it could be argued the thorium-230 and radium-226 in ore dust remain with uranium in the air, this argument is not completely correct for nuclides in the decay chain beyond radon-222, a noble gas. Lead-210 and its daughters may not be bound to the ore dust particles. Because of its high diffusivity, radon is likely to escape the ore dust. Its decay products, therefore, may not be bound to the uranium ore. As a result of this change, separate measurements of the concentration of airborne radionuclides beyond radon-222 are now required. The requirement for separate measurements for lead-210 and its daughters has been made without opportunity for public comment. The Commission has found such opportunity for comment unnecessary since the amendment will not have a significant impact because the concentrations of lead-210 and its daughters in mills are presently far below Part 20 limits.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 and sections 552 and 553 of title 5 of the United States Code, the following amendments of Title 10, Chapter I, Code of Federal Regulations, Part 20 are published as a document subject to codification.

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[1] A "working level" month is defined as exposure to radon daughter concentrations of one "working level" for 170 hours, the usual number of working hours in a month.

40 FR 58847
Published 12/19/75
Effective 1/19/76

Change of Terminology for "As Low As Practicable" Limits

See Part 50 Statements of Consideration.

41 FR 16445
Published 4/19/76
Effective 4/19/76

Miscellaneous Changes to Chapter

Notice is hereby given of the amendment of the Nuclear Regulatory Commission's regulations in 10 CFR Parts 20, 30, 31, 32, 35, 40, 50, 55, 70, 73, 140, and 150 which are of a minor nature.

On March 3, 1975, the Commission published in the FEDERAL REGISTER a revision of Chapter I of Title 10 of the Code of Federal Regulations to reflect organizational and procedural changes effected or made necessary by the Energy Reorganization Act of 1974.

The amendments of the Commission's regulations set forth below, in conformity with the revised organization and current procedures, change the addresses to which various reports and copies thereof should be sent by licensees. The amendments also specify particular offices to which reports should be addressed rather than a general directive to send reports to the Commission. The amendments do not add any new reporting requirements and do not change the substantive requirements for such reports.

Because these amendments relate solely to minor matters, the Commission has found that good cause exists for omitting notice of proposed rule making, and public procedure thereon, as unnecessary, and for making the amendments effective April 19, 1976.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Parts 20, 30, 31, 32, 35, 40, 50, 55, 70, 73, 140, and 150 are published as a document subject to codification.

41 FR 18300
Published 5/3/76
Effective 6/2/76

Preservation of Records

On October 15, 1974, the Atomic Energy Commission published in the FEDERAL REGISTER (39 FR 36871) proposed amendments of its regulations in Parts 20, 30, 31, 32, 34, 40, 50, 55, 70, 115, and 150 which would prescribe time periods for applicant and licensee retention of certain records, and provide that if a retention period is not otherwise provided, such records shall be maintained by the licensee or applicant until the Commission authorizes their disposition. Interested persons were invited to submit written comments and suggestions for consideration in connection with the proposed amendments by November 29, 1974.

Subsequently, in accordance with the Energy Reorganization Act of 1974, Pub. L. 93-438, the Nuclear Regulatory Commission was established on January 19, 1975 and assumed the licensing and related regulatory functions of the former Atomic Energy Commission.

After consideration of the comments on the proposed rule and other factors involved, the Nuclear Regulatory Commission has adopted the proposed amendments, with certain modifications, in the form set forth below.

A majority of the comments suggested deletion or modification of the proposed amendments of sections VII and XVII of Appendix B of Part 50 which would have required that quality assurance records be "maintained for the lifetime of the facility". The proposed amendments of sections VII and XVII of Appendix B are not being adopted at this this time. Licensees will continue to be required to retain quality assurance records for the periods specified in the technical specifications of their license or in other appropriate regulatory provisions.

A commenter suggested that the amendments be revised to include references to other documents in addition to regulatory provisions, license conditions and technical specifications and to specify which document would be controlling in the event the documents provide for different retention periods for the same records. The amendments set forth below provide that the regulations would be controlling in all cases unless the Commission has granted a specific exemption from the record retention requirement specified in the regulations under the applicable regulatory provision for granting such exemptions.

The proposed amendment of § 50.59(b) would have required that records of changes in the facility and in procedures, and records of tests and experiments, be maintained for the lifetime of the facility. One commenter suggested that § 50.59(b) be amended to require that records of changes in the facility and records of tests and experiments be maintained for at least the duration of the license and the records of changes in procedures be maintained for a period of two years from the date of change. A second commenter objected to including "tests and experiments" in this category of preservation for the lifetime of the facility since this provision would be more restrictive than ANSI Standard N 45.2.9-1974 and would not be consistent with Technical Specifications for some licenses. The proposed amendment of § 50.59(b) has been modified to (1) require that records of changes in the facility be maintained until the date of termination of the license, and (2) require that records of changes in procedures and records of tests and experiments be maintained for a period of five years.

It was suggested also that the Commission review the need for maintenance of specific categories of records and the specific maintenance periods for these records, revise the proposed amendments, and publish the revision as proposed amendments for comments. In view of the number of comments received in response to the proposed rule, it is the Commission's view that issuance of a revised proposed rule would not develop additional substantive comments. Further, the recordkeeping requirements in the regulations have been the subject of rule making actions prior to their adoption and the rule which is the subject of this notice does not change or add to the records requirements except with respect to the retention periods.

It was recommended also that after adoption of the rule the Commission should assure that records maintenance requirements of all Agreement States are, or will be within a relatively short time after adoption of the rule, identical to those of the Commission. This recommendation has not been adopted since compatibility of the Commission—Agreement State programs for the regulation of materials covered by the agreements does not require that the pertinent regulations be identical.

Paragraph 40.61(c)(1) has been revised to provide that if source material is combined or mixed with other licensed material and subsequently treated in a manner which makes direct correlation of a receipt record with a transfer, export, or disposition record impracticable, evaluative techniques such as first-in-first-out may be used for purposes of the records retention requirements of § 40.61(c)

Paragraph 70.51(b)(3) has been amended to require that records of receipt, acquisition, inventory, or import of special nuclear material be maintained for five years following transfer or export of such material, and to require that records of inventory maintained to demonstrate compliance with Paragraph 70.58(h) shall be maintained for six months. Paragraph 70.51(b)(4) has been changed to require that records of export of special nuclear material be retained for five years after the export is made. Paragraph 70.51(b)(5) has been amended to require that records of transfers of special nuclear material between material balance areas required by § 70.51(e)(1)(v) be maintained for five years.

Language has been included in the rule set forth below to clarify that the required records may be either the original or a reproduced copy or microform provided that the reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of reproducing a clear and legible copy after storage for the period specified by Commission regulations.

It was recommended that the proposed rule be revised to delete all requirements to maintain records indefinitely and to replace such provisions with a requirement to furnish a copy of the record to the Commission upon termination of the license or permit authorizing the activity. The suggestion that copies of records be furnished to the Commission has not been adopted since it would not be possible as a practical matter for the Commission to accept and retain all such records generated by licensees. The word "indefinitely" has been deleted in the pertinent language. Thus, where a specific retention period is not provided, the amendments provide that the records shall be maintained by the licensee or applicant until the Commission authorizes their disposition.

The rule set forth below requires that records of tests showing compliance with the requirements of § 31.5(c)(2) be maintained for one year after the next required test is performed or until the sealed source is transferred or disposed of. Records showing compliance with the requirements of § 31.5(c)(3) must be retained for a period of two years after the date of the recorded event or until the device is transferred or disposed of. Paragraph 34.25(c) requires that records of leak tests of radiographic sources be maintained for 6 months after the next required leak test is performed or until the source is transferred or disposed of.

Section 32.52 is amended to require that records of transfer of byproduct material in devices generally licensed under § 31.5 shall be maintained for a period of five years after the transfer.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to 10 CFR Parts 20, 30, 31, 32, 34, 40, 50, 55, 70, and 150 are published as a document subject to codification.

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41 FR 52300
Published 11/29/76
Effective 12/29/76

PART 20—STANDARDS FOR PROTECTION AGAINST RADIATION

Exposure of Individuals to Concentrations of Radioactive Materials in Air in Restricted Areas

On August 21, 1974, (39 FR 30164) the Atomic Energy Commission published in the FEDERAL REGISTER proposed amendments to 10 CFR Part 20 concerning control of internal occupational exposures to radioactive materials including provision for use of respiratory protective equipment. The availability of drafts of a related regulatory guide on acceptable programs for respiratory protection and of a related manual of respiratory protection against radioactive materials was also announced in the notice of proposed rule making.

Interested persons were invited to submit written comments or suggestions for consideration in connection with the proposed amendments by October 7, 1974, and the comment period was extended, upon request, to November 6, 1974. In addition, copies of the draft guide and manual were provided in response to requests.

Licensing and related regulatory functions of the AEC were transferred to the NRC pursuant to section 201 of the Energy Reorganization Act of 1974.

After consideration of the comments received and other considerations, the Nuclear Regulatory Commission has adopted the proposed amendments to Part 20 published for comment, with certain clarifying modifications and editorial changes. The more important changes, based largely on the comments received, are summarized as follows:

Since the limits on exposure to airborne radioactive materials are now expressed in terms of intake of such materials into the body, it was suggested that reference be made in the regulation (§ 20.103(a)(1)) to some standardized bases for estimating intake. Accordingly, the effective rule includes a reference to an NRC Regulatory Guide on acceptable concepts, models, equations and assumptions for a bioassay program (Regulatory Guide 8.9).

The intake limits for certain mixtures of uranium in soluble form (§ 20.103(a)(2)) have been changed to conform with those adopted by the Atomic Energy Commission on July 29, 1974 (39 FR 23990).

Licensees may, under the amended regulation, ordinarily control exposures to radioactive materials in much the same way as they do under the regulation before amendment. For example, if from measured concentrations of radioactive materials in air, and from generally known work patterns and staytimes in airborne radioactivity areas, it can be ascertained that no exposure of an individual in excess of the quarterly limit could occur, individual estimates of intake of radioactive material would not be required. In those circumstances where the licensee finds it necessary to maintain individualized records of intake estimates, a requirement to record very small assessments of intake could result in burdensome and unnecessary recordkeeping. To avoid such a requirement the effective regulation has been clarified so that assessment of individual intakes less than specified amounts need not be included in such records (§ 20.103(a)(3)). Licensees might, of course, maintain notes of individual entry into airborne radioactivity areas through "work permit" or similar means, for purposes such as checking effectiveness of respiratory protection programs, without estimating intakes and maintaining individual intake records unless they were needed.

Some commenters were concerned that Regulatory Guide 8.15, which is referenced in the amended § 20.103(c), might be changed without sufficient notice to licensees. Changes to the guide would result in a redating or renumbering of the guide with appropriate changes to § 20.103(c) including prior public notice and procedures thereof in the FEDERAL REGISTER. In addition, a draft of Regulatory Guide 8.15 and its associated manual were noticed with publication of the proposed rule and made available for comment even before adoption of the present procedures.

While no reference is made in the new rule to allowance for particle size in determining exposures to airborne radioactivity, licensees may continue to apply for an exception for such allowance under the provisions of § 20.501.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, and sections 552 and 553 of the United States Code, the following amendment to Title 10, Chapter 1, Code of Federal Regulations, Part 20, is published as a document subject to codification.

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42 FR 20138
Published 4/18/77
Effective 4/18/77

Corrective and Minor Amendments to Chapter

See Part 0 Statements of Consideration.

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42 FR 64619
Published 12/27/77
Effective 3/14/78

PART 20—STANDARDS FOR PROTECTION AGAINST RADIATION

Caution Signs, Labels, Signals, and Controls

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: This rule establishes additional requirements to improve safety in the use of and reduce the probability of accidental exposure of workers to sealed radioactive sources that produce very high levels of radiation. The rule applies to such sources when they are used in devices (called irradiators) to irradiate materials for various purposes (e.g., sterilization of medical products, studies of radiation effects on materials). The amendment was developed in response to the occurrence of a serious overexposure to a high-level radiation source at a licensee's irradiator.

EFFECTIVE DATE: These amendments become effective on March 14, 1978.

NOTE.—The Nuclear Regulatory Commission has submitted this rule to the Comptroller General for such reviews as may be appropriate under the Federal Reports Act, as amended, 44 U.S.C. 3512. The date on which the reporting requirement of this rule becomes effective, unless advised to the contrary, accordingly reflects inclusion of the 45-day period which that statute allows for such review (44 U.S.C. 3512(c)(2)).

FOR FURTHER INFORMATION CONTACT:

Frederick Combs, Office of Nuclear Material Safety and Safeguards, Materials Licensing Branch, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, 301-427-4232.

Jerrold L. Caplin, Office of Standards Development, Occupational Health Standards Branch, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, 301-443-6920.

SUPPLEMENTARY INFORMATION: On May 3, 1976, the Nuclear Regulatory Commission published a proposed amendment in the FEDERAL REGISTER (41 FR 18320) to § 20.203 of the Commission's regulations to require additional controls to reduce the likelihood of personnel exposure to life-threatening radiation doses in short periods of time. The proposed amendment was developed in response to the occurrence of a serious overexposure to a high-level radiation source at a licensee's irradiator.

Interested persons were invited to submit written comments or suggestions for consideration in connection with the proposed amendments by June 17, 1976. Licensees were also invited to comment on alternative safety measures to those proposed and on the amount of time it might take to achieve compliance with the proposed regulation.

All of the 18 comments received acknowledged the need for strong controls over the use of highly radioactive sources. Several commenters said that their facilities were essentially already in compliance with the proposed regulation or that they could comply with such a regulation by making relatively simple and inexpensivve modifications to their existing facilities or operations. Some commentators offered very specific suggestions which, while appropriate for operations at a particular facility, were not of sufficiently broad applicability to be incorporated into a regulation. However appropriate suggestions of this sort might be suitable and will be considered for inclusion in a regulatory guide for applicants for licenses to operate an irradiator.

A few commenters felt that the proposed application of the requirements to facilities such as research reactors or certain radiographic devices would be inappropriate. And others felt that it would be impractical or too expensive to apply the requirements in facilities where the source must be moved about to a variety of non-standard positions. These comments have been accommodated in the amendments either by limiting the applicability of the requirements to irradiators or by permitting the relatively few licensees with particular needs, such as those for special source placement or location, to comply with the regulations by proposing and receiving NRC approval of alternative safety measures that will provide an equivalent degree of safety.

After consideration of the comments received and other considerations, the Nuclear Regulatory Commission has adopted the proposed amendments to Part 20 with certain clarifying modifications and other changes, the more important of which are summarized as follows:

The prefatory language of § 20.203(c)(6) has been modified to make clear that the sources to which the new requirements apply are irradiator sources. A footnote has been added explicitly to specify those sources that are not included in the new requirements.

Paragraph (c)(6)(i) has been modified to eliminate the requirement for an indicator to signal that each entry control device is functioning. The reason for eliminating the requirement is that irradiators frequently are left to function automatically for extended periods when there would be no operator to note the indication of failure of normal function. Furthermore, other provisions of the amendments require that backup devices function to sound alarms and to reduce the radiation levels when the primary entry control devices fail. Since the "fail-safe" circuitry for many entry control devices would make it very difficult to provide such an indicator, the Commission believes that the benefit of having such an indicator is outweighed by the problems accompanying its installation. Paragraph (c)(6)(i) has also been changed to clarify that the radiation levels to be reduced are those from the sealed irradiation source itself, and that the entry control device must function not only to reduce the level of radiation but also to prevent the source from being placed in operation until the control system is functioning properly.

Paragraph (c)(6)(ii) has been changed to clarify that the additional controls required therein must operate upon failure of the entry control devices to function as required by paragraph (c)(6)(i).

Paragraph (c)(6)(iii) has been modified to make it clear that the physical radiation barriers referred to are those other than the source's storage container or permanent structural components such as walls that have no credible likelihood of failure in ordinary circumstances. A requirement has also been included in this paragraph for monitoring the storage shield's integrity when the shield is a liquid.

Paragraph (c)(6)(vii) has been changed to allow continuous operations to proceed without daily entry control checks unless operations are interrupted and then resumed.

Requirements have been included in (c)(6)(viii) for the control of those materials entry and exit portals to the irradiation area that are not intended for use by individuals.

A paragraph (c)(7) has been included to provide allowance for the use of alternative safety measures in facilities with special requirements.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and Sections 552 and 553 of the United States Code, the following amendment to Title 10, Chapter 1, Code of Federal Regulations, Part 20, is published as a document subject to codification.

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43 FR 22171
Published 5/24/78
Effective 6/23/78

PART 20—STANDARDS FOR PROTECTION AGAINST RADIATION

Removal or Defacing of Radioactive Materials Labels on Empty Containers

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations establishing standards for protection against radiation hazards arising out of NRC licensed activities to require the removal or the defacing of radioactive labels on empty, uncontaminated containers prior to disposal. The action is taken in response to a petition from the Department of Military Affairs, State of Alaska and is designed to reduce the number of required investigations concerning radioactive containers disposed of improperly.

EFFECTIVE DATE: June 23, 1978.

FOR FURTHER INFORMATION CONTACT:

Dr. Lewis Battist, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, 301-443-6900.

SUPPLEMENTARY INFORMATION: In response to a petition from the Department of Military Affairs, Alaska Disaster Office, the Commission is hereby amending its rules, specifically 10 CFR Part 20, to require licensees to obliterate or mutilate the radioactive symbols or labels from empty radioactive material containers prior to disposal or clearly indicate that the container no longer contains radioactive material. In the event such action is not feasible, then a placard or label bearing the word "empty" should be attached.

Notice of the petition for rulemaking (Docket Number PRM 20-8) was published in the FEDERAL REGISTER on February 22, 1977 (42 FR 10377) and public comment solicited. The Commission after considering the proposed rule published its intent to adopt this rule on July 14, 1977 (42 FR 36268) and invited public comment. A total of 10 comments were received in response to this FEDERAL REGISTER notice. Seven of these comments were in favor of this rule.

Two of the replies that were in favor of the proposed rule requested NRC to establish a residual activity or contamination limit to be applied to containers for uncontrolled disposal. The establishment of residual activity levels is beyond the scope or intent of the petition under consideration. One respondent expressed concern over the volume of labels that they would have to deface or destroy and stated that they would petition the NRC to accept compaction as a viable alternative to defacing or destroying the radioactive materials label. Compaction is an acceptable method for disposal, provided that any subsequently visible labels are removed or defaced.

Three of the replies were not in favor of the proposed rule. The concern expressed or implied in these comments was that full containers bearing radioactive materials labels would have the labels removed and then be discarded as ordinary trash. Such improper behavior could not be prevented by rulemaking. The negative respondent further expressed the desire that those individuals who dispose of improperly labelled containers be tracked down and cited. At the present time containers bearing the radioactive materials label, but not containing any radioactive material, may be disposed of in any manner. It is these empty containers that have been found in the environment. Promulgation of this rule is intended to eliminate this practice which resulted in responding to false alarms and to establish regulatory authority whereby violators can be cited.

Overlooked by the negative respondents is that the rule pertains to "empty uncontaminated containers." This requires a determination or knowledge of this fact on the part of the licensee at the time of disposal that these conditions have been met which further reduces the likelihood that contaminated containers will get into the surplus container trade.

The rule primarily pertains to shipping and other outer containers that do not ordinarily come into contact with radioactive materials. Present regulations, § 20.205 of 10 CFR Part 20, requires licensees to inspect and survey, upon receipt, packages containing radioactive materials. Any packages that are contaminated or have excessive radiation levels require notification of the shipper and the NRC. Any necessary action is taken at the time to prevent improper disposal practices and insure that the health and safety of the public are protected. Implementation of this rule requires a knowledge on the part of a licensee that the container being discarded is "empty and uncontaminated".

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendment of Title 10, Chapter I, Code of Federal Regulations, Part 20, is published as a document subject to codification.

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43 FR 29270
Published 7/7/78
Effective 7/7/78

PART 20—STANDARDS FOR PROTECTION AGAINST RADIATION

Clarifying Amendments

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: When § 20.103 of the Commission's Standards For Protection Against Radiation was amended recently the amendments did not indicate that radon-222 and its daughters may be averaged over 1 year, as specified in footnote 3 to appendix B of the Standards for Protection Against Radiation. This is clarified by the amendments set forth below. Minor editorial changes also are made.

EFFECTIVE DATE: July 7, 1978.

FOR FURTHER INFORMATION CONTACT:

> Dr. Stephen A. McGuire, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, phone 301-443-6920.

SUPPLEMENTARY INFORMATION: When § 20.103 of Part 20 was amended recently the amendments did not indicate that exposure to radon-222 and its daughters may be averaged over one year, as specified in footnote 3 to appendix B in Part 20. This is clarified by the amendments set forth below.

The following sentence is added as the first sentence in footnote 2 of § 20.103.

> For radon-222, the limiting quantity is that inhaled in a period of one calendar year. * * *

In the final sentence of footnote 2, the word "materials" is changed to "nuclides".

The following sentence is added to footnote 3 of § 20.103:

> * * * Multiply the concentration value specified in appendix B, table I, column 1, by 2.5×10^9 ml to obtain the annual quantity limit for Rn-222.

In § 20.405(a) the words "exposure of persons" are changed to "exposure of individuals".

Because these amendments relate solely to minor matters, the Commission has found that good cause exists for omitting notice of proposed rule making, and public procedure thereon, as unnecessary, and for making the amendments effective on July 7, 1978.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 20 are published as a document subject to codification.

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43 FR 44827
Published 9/29/78
Effective 12/13/78

PART 20—STANDARDS FOR PROTECTION AGAINST RADIATION

Personnel Monitoring Reports

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations to extend to all NRC specific licensees the requirement for submission of an annual statistical summary report on radiation exposure of workers. The existing requirement applies only to four categories of licensees that were considered to involve the greatest potential for significant occupational exposures, i.e., nuclear power reactors, industrial radiographers, nuclear fuel processors and reprocessors, and certain large commercial suppliers of byproduct materials. The amendments do not involve any changes in the requirements for the provision and use of personnel monitoring equipment or the records of personnel monitoring data that must be kept by licensees. The changes relate solely to reporting data already being recorded. The regulation requiring certain reports on termination of employment or work assignment in the facilities of the four categories of licensees is being amended only to change the recipient of the reports and to specify the same four categories of licensees.

Those categories are currently set out in another section and incorporated by reference in the section requiring termination reports.

EFFECTIVE DATE: December 13, 1978.

NOTE.—The Nuclear Regulatory Commission has submitted this rule to the Comptroller General for such reviews as may be appropriate under the Federal Reports Act, as amended, 44 U.S.C. 3512. The date on which the reporting requirement of this rule becomes effective, unless advised to the contrary, accordingly reflects inclusion of the 45-day period which that statute allows for such review (44 U.S.C. 3512(c)(2)).

FOR FURTHER INFORMATION CONTACT:

> Mr. Walter S. Cool, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 telephone 301-443-5970.

SUPPLEMENTARY INFORMATION: On May 30, 1975, the Nuclear Regulatory Commission (NRC) published in the FEDERAL REGISTER (40 FR 23478), a notice of proposed amendments to 10 CFR Part 20 that would extend to all NRC specific licensees the requirements of § 20.407 for the submission of an annual statistical summary report of estimated whole body radiation doses. Section 20.408 would be amended only to specify the same four categories of licensees presently required to submit reports of individual exposure to radiation and radioactive material upon termination of employment or work assignment in their facilities. Those categories are currently set out in § 20.407(a) and incorporated in § 20.408 by reference.

By letter dated June 2, 1975, copies of the notice of proposed rulemaking were sent to all specific licensees. A majority of the 36 comments submitted in response to the notice of proposed rulemaking favored the amendments, but offered some suggestions for change. Many of the commenters who opposed the proposed amendments were medical licensees who expressed opposition to the filing of any additional reports. They noted that additional paperwork increases cost of health care delivery, and hence is inflationary. Opinions were expressed that the proposal might have theoretical value, but would not be practical, that insufficient need has been shown for another administrative requirement with low benefit/cost ratio, that occupational exposures (in medical diagnosis and therapy) are "as low as practicable", that the existing requirement (§ 20.403) for reporting overexposures is quite adequate to make licensees aware of their responsibilities in cases of overexposure and only licensees with repeated overexposures should be asked to submit annual statistical summary reports, that it is not possible to separate exposures received while working with NRC-licensed material from exposures received while working with X-ray, radium, or other radiation sources not subject to NRC regulations, and that there are inherent inaccuracies in personnel monitoring data. One commenter suggested that NRC send each licensee (1) a summary of the data collected, and (2) a reminder of the reporting requirement and a form suitable for recording the data. One commenter indicated a need for a longer time period in which to prepare the report. Some commenters misunderstood the proposed amendment to § 20.408, believing that it would extend to all licensees the requirement for reports of individual exposures upon termination of employment with a licensee or work assignment in the licensee's facility.

In view of the comments that raised questions regarding the value and impact of the proposed amendments, the Commission staff requested, by letter dated August 25, 1976, the voluntary, one-time submission of the personnel monitoring data for 1975 by all NRC specific licensees. The letter also invited the licensees to provide an estimate of the cost of their effort (1) in man-hours, and (2) in total cost of preparing the report. The distributions of the 172 responses that estimated man-hours and of the 125 responses that estimated total cost indicated a median commitment of 2.75 minutes or $0.65 per monitored individual. The personnel monitoring and cost data have been published as NUREG-0419.

The Commission is convinced, based on 9 years of experience with reports filed by four categories of licensees pursuant to § 20.407 and based on the results of the one-time submission of data for 1975 by other categories of licensees, that it is necessary to the Commission's functions to receive the annual statistical summary reports. The data are essential to the evaluation of the risk of radiation exposure associated with activities conducted in licensed facilities. The data will permit evaluation of exposure trends. They also permit some assessment of the degree of radiation protection efficiency that is being maintained, one indicator of the effectiveness of the Commission's regulatory program. The Commission recognizes the diversity of programs conducted by licensees, but believes that there is sufficient basis for comparison of exposure experience among types of licensees and among licensees within each type. The NRC believes that licensees need to develop this information for their own evaluation and action in control and direction of their radiation safety programs. Consideration of the data led to the development of Regulatory Guides 8.8, "Information Relevant to Ensuring that Occupational Radiation Exposures at Nuclear Power Stations Will Be As Low As Is Reasonably Achievable," and 8.10, "Operation Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable," and will assist in the identification of situations to be studied further in order that regulations and regulatory guides can be developed on action that should be taken in the design and operation of licensed facilities to assure that in-plant exposures are kept as low as is reasonably achievable. The data were used in the consideration of occupational exposure aspects of controlling radioactive effluent releases from nuclear powerplants in Appendix I, 10 CFR Part 50, and have been used to develop a variety of value/impact analyses. They may be used as one indicator in the assignment of priorities for inspection and enforcement actions. The data are being used to establish priorities with respect to the need for regulatory attention through consideration of the collective dose in addition to individual and average doses. In some cases, more regulatory attention may be required for licensees with larger collective doses than for licensees with larger individual doses.

It should be noted, however, that the personnel monitoring data do not permit evaluation of what occupational exposures are "as low as is reasonably achievable." Such evaluation requires study of the specific factors associated with a specific facility and activity.

The Commission has considered alternative methods of obtaining information on the number and exposure experience of individuals working in licensed facilities and found them to be unsatisfactory by reason of cost or data content. The burden on respondent licensees under the reporting requirement of § 20.407 will not be large and will, of course, be roughly proportional to the number of individuals monitored by a licensee. The Commission considers the burden well justified. However, the Commission has decided to impose the extended requirement only for a trial period of 2 years. That is, reports by all licensees are to be filed within the first quarter of calendar years 1979 and 1980, providing personnel monitoring data for the years 1978 and 1979, respectively. The Commission will evaluate the data for those 2 years, and the benefits derived therefrom and will consider whether or not to extend or otherwise modify the reporting requirement. A notice of proposed rulemaking will be published regarding any such extension or modification and opportunity for public comment will be provided. Note that the requirement for reporting by the four categories of licensees previously required to report, and now specified in § 20.408(a), as amended, will continue in any case.

The Commission does not consider it sufficient that licensees merely maintain exposures of individuals within the limits of 10 CFR Part 20, thus avoiding overexposures Rather, § 20.1(c) states that licensees should make every reasonable effort to maintain radiation exposures, and releases of radioactive materials in effluents to unrestricted areas, as far below the limits specified in 10 CFR Part 20 as is reasonably achievable. There are, without doubt, many specific situations where occupational exposures are as low as reasonably achievable. However, because of the lack of data on exposures being experienced by a large fraction of licensees and the need to know the specific circumstances involved in order to determine when occupational exposures are as low as is reasonably achievable, the Commission believes that a categorical statement regarding any type of licensee or type of facility as achieving that goal would be premature and unfounded at this time.

The Commission recognizes the limitations of personnel monitoring devices and the possible differences between data obtained from routine monitoring programs and the actual doses received by individual workers. However, the Commission believes that current personnel monitoring measurements sufficiently characterize the radiation environment in which the individual works to provide an adequate basis for radiation protection evaluation purposes, and desires to be informed as to the estimated exposures actually being recorded.

The Commission also recognizes that statistical summary reports will not permit evaluation of the dose contribution from different types of activities within the licensee's program or identification of contributions to the total dose received during work with unlicensed sources of radiation. However, licensees are required (§ 20.1(b)) to control the possession and use of licensed material in such a manner that the total occupational dose received by individuals from both licensed and unlicensed sources in the licensee's possession does not exceed the standards in 10 CFR Part 20. Thus, licensees should monitor the individual's total occupational dose (§ 20.202), record the estimated dose in the individual's record (§ 20.401), and use the total dose estimate in preparing the annual statistical summary report required by § 20.407, as amended, and the termination report required by § 20.408, if applicable. Note that §§ 20.407 and 20.408 have been amended to change the recipient of the reports from the Director of Inspection and Enforcement to the Director of Management and Program Analysis, NRC.

The Commission has reminded each of the licensees who have been subject to the reporting requirement of the need to report each year, including a copy of the table of estimated whole body exposure ranges that may be used in filing the report. The Commission proposes to continue this practice. Licensees will be reminded that if personnel monitoring was not required to be provided to any individual (§ 20.202(a) or § 34.33(a)) during the calendar year, licensees are required to submit a simple statement to that effect, only. The Commission cannot determine from the issuance of a license whether personnel monitoring is or is not required, because radioactive material licensed for possession and use may not be procured, and licensed operations may be suspended such that monitoring is not required.

The simple negative report is included to reduce the number of cases in which followup action might be necessary in the absence of a report being filed by a licensee. The burden of a responding licensee in filing the negative report is very small. The data on personnel monitoring are summarized each year in a report to the Commission and are available to the public.

Discussions with several commercial dosimetry services indicate that there is very little need for more than 3 months in which to file the annual statistical summary report. It was indicated that sometimes delay may occur because of the late submission of dosimeters for processing, and that in some cases the exposure records are not summarized and the report prepared until after the first monitoring period in the new calendar year in an effort to include individuals whose dosimeters were not submitted on time for evaluation at the end of the year. Experience indicates that a very small number of "lost badges" and other causes of incomplete data will persist regardless of the date established for filing of the report. Further, it does not appear that the annual statistical summary report would be significantly improved by delaying the date for filing of the report. There should not be additional cost to licensees to process their data during the first calendar quarter of each year.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 20, are published as a document subject to codification.

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44 FR 32349
Published 6/6/79
Effective 8/20/79

10 CFR Parts 19 and 20

Control of Radiation Exposure to Transient Workers

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its standards for protection against radiation. The amendments require NRC licensees to control the total occupational radiation dose of individuals who work in NRC-licensed activities. Implementing changes require licensees: (a) to obtain from a prospective employee information on occupationally related doses received during a current calendar quarter from sources outside of the licensee's control if there is a chance that the employee may subsequently receive a dose in excess of 25% of the regulatory standards in the facility of the new employer; (b) to furnish prompt estimates of occupational dose, at the request of the individual, upon termination of work; and (c) to keep associated records. The amendments are intended to minimize the possibility of overexposure of (a) short-term workers, sometimes called "transient workers," and other individuals who may be employed by, or work in the restricted areas of, more than one licensee within a single calendar quarter and (b) individuals who may work for more than one licensee at a time (moonlighters).

EFFECTIVE DATE: August 20, 1979.

Note.—The NRC has submitted this rule to the Comptroller General for such reviews as may be appropriate under the Federal Reports Act, as amended, 44 U.S.C. 3512. The date on which the reporting and record keeping requirements of this rule become effective, unless advised to the contrary, accordingly reflects inclusion of the 45 day period which that statute allows for such review (44 U.S.C. 3512(c)(2)).

FOR FURTHER INFORMATION CONTACT: Mr. Walter S. Cool, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (phone 301–443–5970).

SUPPLEMENTARY INFORMATION: On February 8, 1978, the NRC published in the Federal Register (43 FR 4865) a notice of proposed amendments to 10 CFR Parts 19 and 20 designed to minimize the possibility of overexposure of transient and moonlighting workers. By letter dated February 13, 1978, copies of the notice of proposed rule making were sent to all NRC specific licensees. The notice provided a period of sixty (60) days for public comment. Copies of a value/impact assessment of the proposed amendments prepared by the NRC staff were sent to individuals who requested further information.

After careful consideration of the comments on the notice of proposed amendments and the other factors involved, the Commission has adopted the amendments in effective form with the minor changes discussed below.

Forty-one comments were received in response to the notice. Of these, twenty-one stated agreement with the concept of controlling the total occupational dose to workers; eight stated opposition to the proposed amendments. Many of the commenters expressed concern about some aspect of the proposed amendments, or suggested improvements. Several offered suggested changes in sections of the regulations not directly involved in the proposed amendments.

A number of commenters did not appear to understand that the proposed amendments would apply only to situations in which a licensee permits an individual to receive up to 1.25 rems per calendar quarter without obtaining information on prior radiation exposure, as provided by § 20.101(a), 10 CFR Part 20. Some of the commenters erroneously interpreted the proposed amendments to require a licensee to obtain exposure histories from previous employers of all new workers, as is currently required by §§ 20.101(b) and 20.102, 10 CFR Part 20, before permitting an individual to receive up to 3 rems per quarter within the 5(N–18) dose averaging formula. The licensee may, of course, do so. However, it is the Commission's intent that the worker would provide the licensee-employer with the exposure data stated on an estimate provided at termination by a previous licensee. It is recognized that workers for various reasons may not have the estimates when reporting for work, and the amendments require a licensee to obtain only a signed statement from the worker, without verification with previous employers, of the exposure received by the individual during the current calendar quarter.

This provision avoids the concern expressed by one commenter that a licensee may be unable to obtain information on occupational dose received by an individual during prior work in operations not licensed by the NRC.

The Commission has not changed the degree of flexibility available to licensees in designating calendar quarters (§ 20.3(a)(4)), as recommended by some commenters. While it is recognized that some short-term workers may receive two exposures approaching 1.25 rems in a short period of time due to the difference in calendar quarters being used by two licensees, the NRC staff believes that the probability of this happening is acceptably small. The wording of § 19.13(e) and § 20.102(a) require both the licensee providing an estimate of dose at termination, and the individual providing a subsequent licensee-employer with a signed statement regarding prior dose, to specifically identify the calendar quarter involved. Further, there were reasons for providing the degree of flexibility in the designation of calendar quarters during previous rule making actions. They included the need to accommodate different monitoring periods being used (weekly, bi-weekly, monthly, quarterly) and the need to permit some spread of the work load of persons providing personnel monitoring services.

Other commenters stated that the amendments imply that a licensee can be required to furnish personnel monitoring to persons while not under the licensee's control, and that the licensee can be held responsible for occupational dose received at another licensee's facility. Licensees may choose to provide monitoring equipment to their employees while they are assigned to work in another licensee's restricted areas, or while moonlighting, in order to verify the information on exposure provided through the worker by the second licensee. However, each licensee is only required (1) to provide monitoring to each individual in the licensee's restricted area under the circumstances specified in § 20.202, (2) to provide an estimate at termination, if requested, and (3) to account for previous exposure information, made available by the worker, in limiting further exposure to that worker.

The Commission considers it necessary for licensees to control the total occupational dose of workers and does not agree with a number of commenters who consider the implementing controls needlessly restrictive or unduly burdensome on licensees. The Commission has chosen this method and level of implementation after balancing factors including (1) the previous absence of requirement for any effort to determine prior exposure, (2) the need for prompt exposure information permitting control of exposure to transient workers, that is, the information must be available before the individual appears for work at another licensee's restricted area, (3) high cost and technical difficulties associated with alternative methods of controlling total occupational dose, (4) potential concern regarding employability or invasion of privacy, and (5) the likelihood that, in the absence of specification of implementing action that is acceptable to the NRC, many licensees would expend greater effort than may be deemed necessary by the Commission. The proposed amendment to § 20.102(a) would require a licensee to obtain only a statement of prior exposure during the current calendar quarter from any new worker who is likely to receive, in the licensee's restricted area(s), more than 25% of the applicable standards in §§ 20.101(a) and 20.104(a), 10 CFR Part 20, during the balance of the quarter.[1] The Commission believes that a majority of licensees do not experience doses to their workers greater than 25 percent of the standards and, therefore, will not be required to obtain the statement. The proposed new § 19.13(e) would require provision to a worker who requests it, of an estimate (not the finally determined monitoring result) of the dose received during the terminating calendar quarter. The Commission believes that only a small fraction of terminating workers will request the estimate, greatly limiting the potential cost of implementation by licensees.

Note that although the amended regulations require control of the total occupational dose received by workers, the statistical summary report of personnel monitoring data to be filed annually pursuant to § 20.407, and the reports of exposure to radiation and radioactive material to be filed upon termination of employment with specified licensees or completion of a work assignment in the licensee's facility pursuant to § 20.408, should include only that dose received during the specified period of time and while engaged in operations authorized by that license. These reports should not include personnel monitoring data obtained from previous employers of an individual or any estimates of prior dose, in order to avoid duplicate reporting of individual doses.

A number of commenters pointed out that proposed § 19.13(e) was vague as to the time at which the estimate is to be provided to the terminating worker. The wording in § 19.13(e) has been changed to specify that the estimate is to be provided at termination.

Other commenters asked what assumptions a licensee-employer is to make when informed that an individual has received a dose reasonably estimated to be less than 25% of the applicable standards. The licensee would have been permitted to ignore such doses. Further consideration of the small difference in effort required for a licensee to provide a numerical estimate of dose or to provide only a statement that the dose was reasonably estimated to be less than 25% of the applicable standard, has led the Commission to require provision of a numerical estimate.

In the event that an individual informs a licensee-employer about radiation dose received during prior employment during the current calendar quarter, but is unable to provide an estimate of that dose, there are several alternatives available to the licensee. The licensee may: (1) decide not to hire the individual for work involving further exposure because of the unknown dose; (2) hire the individual for work involving only low levels of exposure, less than the criteria under which personnel monitoring equipment is required to be provided, during the remainder of the calendar quarter; or (3) take the effort to obtain the exposure history of the individual from the previous employer. The licensee is not required to obtain additional statements for each individual during subsequent calendar quarters of continued employment, as one commenter assumed.

Questions were raised regarding the reporting of overexposures. In the event that a licensee permits an individual to be exposed such that the total occupational dose, including any personnel monitoring data or estimates of dose provided to the licensee, exceeds the dose-limiting standards, that licensee must report the overexposure to the NRC pursuant to § 20.405, and to the individual pursuant to § 19.13(d), and will be subject to appropriate enforcement action. In the event that the licensee limits exposure of an individual on the basis of the best information available, but finds after the fact, that the finally determined dose of the individual was higher than previously known or estimated and, therefore, the individual exceeded the dose-limiting standards, the NRC and the individual shall be informed, as noted above, but no enforcement action will be taken against the licensee.

One commenter suggested that an exemption be provided to the requirements of §§ 19.13(e) and 20.102(a), as proposed, for non-licensed persons who maintain dosimetry which provides cumulative dose to their employees. The Commission commends such persons for their concern and provision for the protection of their employees. However, the rule was never intended to apply to other than licensees and there is no need for any exemption for non-licensees.

Several commenters noted that there was no indication of the accuracy required for the estimate of dose at termination. This reqirement was omitted deliberately, knowing that some licensees have the capability of providing final determination of personnel monitoring results on short notice while other licensees may have to rely on other mechanisms for estimating dose, such as pocket dosimeter readings or estimating the dose from radiation survey data and associated occupancy time. It is the Commission's intent that licensees should provide the worker with the best exposure information available at the time of termination. This information should be the final determination, if practicable. If pocket dosimeter readings or other means of estimation are used the licensee should apply any correction factors or conservatisms that the licensee has found appropriate to relate the data to finally determined monitoring results. It is the Commission's further intent that a subsequent employer-licensee use this best information, as provided by the worker, and maintain further exposure of the worker as low as is reasonably achievable within the 1.25 rems per calendar quarter standard, including the estimated prior dose. If the finally determined monitoring result for the individual is received during the period of employment of the individual, that result should replace the estimated value. The licensee is required (pursuant to §§ 20.405 and 19.13(d)) to notify the Commission and the individual of an exposure, including the estimate, found to be in excess of the standard, because such an occurrence would indicate a failure by that licensee to control contribution to the individual's dose. By the same token, a licensee will not be found in non-compliance with the regulations if the licensee controlled exposure of the individual within the standards, using the estimate (best information available to the licensee at the time), even though the dose is subsequently found to exceed the standard upon receipt of a finally determined monitoring result.

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[1] One commenter questioned the basis for selecting 25 percent of the applicable standards in §§ 20.101(a) and 20.104(a) as the threshold for requiring licensees to obtain statements of current calendar quarter doses. That value was selected rather arbitrarily but recognizes (1) that, although most licensees provide personnel monitoring to evaluate any potential exposure, such monitoring is not required for exposure below 25 percent of the standard § 20.202, and (2) that there have been very few instances in which an individual terminated employment or work assignment with more than four licensees in a single calendar quarter.

Several commenters noted that the amendments may limit the employability of a worker whose dose has approached or exceeded the standard. Licensees could not allow an individual who has received a dose approaching the standard to be further exposed during the remainder of the calendar quarter in which the exposure occurred, but may allow the individual to receive further exposure, within the dose-limiting standards, in subsequent calendar quarters. The potential for such career interference exists under the present regulations and could be increased by the amendments. The Commission has no basis for estimating the existing or potential increase in impact, but believes it to be small. Many transient workers are highly skilled individuals who are needed to perform certain specialized tasks, often under contracts with a number of licensees. Because of their skills, such workers are very unlikely to lose employment. Rather, they would likely be employed in tasks involving little or no additional radiation dose. Other transient workers are much less specialized and may be hired from local pools to accomplish essential work. These workers would, upon termination, be available for other requests for labor in their area, with low probability of employment with the same or another licensee.

It is recognized that the proposed method of controlling total occupational dose depends upon cooperation by the employee with the licensee in providing information on previous and on-going employment involving radiation dose. The NRC does not exercise direct regulatory control over individual workers, and therefore cannot require individual workers to provide accurate dose information to licensees, and the NRC will not take enforcement action against a licensee solely because an individual worker withholds or falsifies information. While recognizing the potential for economic incentive for a worker to withhold or otherwise falsify dose information, the Commission believes that most individuals who have been instructed in the health protection problems associated with exposure to radiation and radioactive materials pursuant to § 19.12, 10 CFR Part 19, will recognize the benefit to their health and will cooperate with licensees. Further, NRC does not regulate all of the sources of occupational dose. A suggested requirement for licensees to provide monitoring information to subsequent licensee-employers would not apply to operations not licensed by NRC and would, therefore, provide only partial information.

One commenter pointed out that the regulation should require another statement from a worker who is rehired following termination of employment or work assignment in a licensee's restricted area. The words "during each employment or work assignment" have been added to § 20.102(a) to accommodate that comment.

One commenter noted that the proposed amendments addressed transient and moonlighting workers but did not specifically recognize the potential for exposure of individuals who seek secondary employment while temporarily "laid off." The Commission believes that, if the worker has not been terminated, but has some status as an employee, the secondary work is comparable to moonlighting.

The NRC staff has been unable to devise acceptable regulatory methods for controlling the total occupational dose to moonlighters, and concludes that control may be best effected by agreements or conditions of employment between the licensee and the worker. Close cooperation between licensees and workers, including frequent exchange of monitoring information or agreement to limit exposures to fractions of the standards, will be necessary. The potential for labor-management controversy over such working agreements is recognized. The Commission believes that controversy can be minimized in the best interest of the workers and the licensees.

The Commission considered, as one alternative in the development of the proposed regulations, the imposition of short-term dose standards as suggested by one commenter. Short-term standards, such as 100 millirems of whole-body dose per week, or weekly prorated increments of quarterly standards, would have the desirable effects of (1) essentially precluding the possibility of overexposure of transient workers during multiple employments, (2) impacting on only those licensees employing short-term workers, and (3) encouraging increased efforts to reduce doses and dose rates by design and engineering changes. However, this alternative would require the use of larger numbers of workers to accomplish essential work at existing facilities. Because workers are exposed while entering and leaving a work area, and while orienting to the work to be done, as well as during actual performance of the work, the use of more workers would increase the collective (man-rem) dose. This alternative would be costly and unproductive for the licenses and would not assure that moonlighting workers do not receive doses in excess of the standards.

The procedural alternative of imposing controls on the total doses of transient and moonlighting workers by means of technical specifications or license conditions in the licenses of those activities experiencing the use of such workers, suggested by another commenter, was also rejected. The extent of use of short-term or moonlighting workers is not precisely known, and this alternative could result in arbitrary, non-uniform application of the added controls and the burden associated with them.

One commenter noted that the proposed amendments did not require action to control the total exposure of workers to intake of radioactive materials during multiple employments. Such control was considered but has not been proposed or effected at this time. The information available to the Commission, while not comprising the total experience of licensees, indicates that most licensees do not experience exposures exceeding 25% of the standards. Prior to amendment of § 20.103, 10 CFR Part 20, published November 29, 1976 (41 FR 52300), exposure to concentrations of radioactive material in air was limited on the basis of 40 hours during any seven consecutive days. The existing regulation, while controlling the quarterly intake of radioactive materials, requires precautions which are considered to make additional control over exposure during multiple employments unnecessary at this time. Consideration is being given to further amendment to the regulations that would, if adopted, require the summation of risk from external dose equivalent and internal committed dose equivalent.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy

Reorganization Act of 1974, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Parts 19 and 20, are published as a document subject to codification.

45 FR 13434
Published 2/29/80
Effective 2/29/80

10 CFR Parts 20 and 50

Immediate Reporting of Significant Events at Operating Nuclear Power Reactors

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations, effective immediately, to require timely and accurate information from licensees to NRC following significant events at operating nuclear power reactors.

EFFECTIVE DATE: February 29, 1980.

FOR FURTHER INFORMATION CONTACT: Dudley Thompson, Office of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, phone 301-492-8177.

SUPPLEMENTARY INFORMATION: The capability of the NRC to make timely decisions and to provide adequate assurances regarding actual or potential threats to public health and safety, depends heavily on the rapidity with which significant events are communicated by nuclear power reactor licensees to NRC. The majority of events occurring throughout the nuclear industry pose little or no serious or immediate threats to the public health and safety; however, certain events do pose such threats or generate fear or unusual concern.

NRC has an important obligation to collect facts quickly and accurately about significant events, assess the facts, take necessary action, and inform the public about the extent of the threat, if any, to public health and safety. Not only must NRC act promptly to prevent or minimize possible injury to the public, it must also take appropriate action to alleviate fear or concern created as a result of such events.

After the accident at Three Mile Island on March 28, 1979, the NRC staff acted to ensure the timely and accurate flow of information from licensees of operating nuclear power reactors following significant events. Dedicated telephone lines have been installed from all operating power plants to the NRC Operations Center and the Regional Offices. A line is located in each control room with provisions made for extensions to be located at other specified locations at the facility. When these phones are picked up to report significant events, they automatically ring at the NRC Operations Center and can be held open as long as needed.

NRC's Office of Inspection and Enforcement (OIE) issued Bulletins and sent letters requesting each licensee to review its prompt reporting procedures to NRC. These were intended to make certain that each licensee notifies NRC within one hour of the time the reactor is not in a controlled or expected condition of operation. Once the licensee has notified NRC, an open, continuous communication channel is established and maintained between the licensee and NRC.

The NRC staff has continued to evaluate licensees' responses to OIE's Bulletins and letters and to analyze the kinds of significant events that should be reported immediately. By their very nature, OIE's Bulletins and letters did not impose requirements on licensees, and in several instances licensees have not immediately reported significant events to NRC. Moreover, the Bulletins and letters did not describe in sufficient detail the specific types of significant events NRC determined had to be reported immediately. The Commission has found that in order to take necessary action to protect the health and safety of the public, twelve types of significant events should be reported immediately (within one hour) to it. Consequently, NRC has decided to publish a rule requiring the immediate reporting by telephone of these events. The events, which are described in detail in the rule, include serious events that could result in an impact on the public health and safety such as those leading to initiation of the licensee's emergency plan or any section of the plan, the causing of the nuclear power plant to be in an uncontrolled condition, the exceeding of a safety limit, an act of sabotage, or an uncontrolled release of radioactivity. With regard to initiation of the licensee's emergency plan, the Commission is presently in the process of promulgating a rule concerning requirements for emergency plans for nuclear power plants. Meanwhile, the Commission has published guidance on emergency preparedness at operating nuclear power plants in NUREG-0610. This guidance has been sent to all affected licensees.

In view of (1) the significance of these twelve types of events with respect to their ability to jeopardize the health and safety of the public, (2) the fact that most of these events are not required presently to be reported immediately to NRC, (3) the problem of licensees not having reported such events to NRC after receipt of OIE's Bulletins and letters, and (4) NRC's immediate need to know in order to act quickly, NRC has determined that there is good cause to waive the opportunity for the public to comment on this rule before its effective date, and has determined, therefore, that it is in the public interest to make this rule effective immediately.

Although this rule is being published in effective form without a prior public comment period, the public is invited to submit its views and comments. If possible, these comments should be submitted by April 29, 1980. After reviewing any views and comments submitted, the Commission may reconsider or modify the rule as it deems necessary.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to 10 CFR Part 20 and 10 CFR Part 50 are published as a document subject to codification.

45FR14199
Published 3/5/80
Effective 3/5/80

Minor and Clarifying Amendments

See Part 1 Statements of Consideration

45 FR 71761
Published 10/30/80
Effective 1/28/81

10 CFR Part 20

Standards for Protection Against Radiation; Burial of Small Quantities of Radionuclides

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations to require NRC licensees to obtain specific approval to bury small quantities of radionuclides. Current NRC regulations provide that licensees may bury certain small quantities of radionuclides without prior approval. The amendments will provide greater assurance that buried radioactive material will not present a health hazard.

EFFECTIVE DATE: January 28, 1981.

Note.—The Nuclear Regulatory Commission has submitted this rule to the Comptroller General for such review as may be appropriate under the Federal Reports Act, as amended, 44 U.S.C. 3512. The date on which the reporting requirement of this rule becomes effective, unless advised to the contrary, reflects inclusion of the 45-day period which that statute allows for such review (44 U.S.C. 3512(c)(2)).

FOR FURTHER INFORMATION CONTACT: Mr. John W. N. Hickey, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (phone: 301–443–5966).

SUPPLEMENTARY INFORMATION: On December 4, 1978, the Nuclear Regulatory Commission (NRC or Commission) proposed to delete § 20.304 of 10 CFR Part 20, "Standards for Protection Against Radiation" (43 FR 56677). Section 20.304 allows licensees to bury certain small quantities of radionuclides without prior NRC approval.

As discussed in the notice of proposed rulemaking, several State representatives have suggested that the risk from burials of radioactive waste allowed by § 20.304 may be unacceptable. The quantities of radionuclides allowed to be buried pursuant to § 20.304 are 1,000 times greater than exempt quantities. Such quantities pose a small risk if they are properly buried and left undisturbed, particularly if they are dispersed through a large volume of waste material. However, § 20.304 imposes no concentration limits, and the quantities as concentrated "point sources" are potentially large enough to cause excessive radiation exposures if the radioactive material is mishandled, improperly buried, or disturbed after burial. For example, § 20.304 allows burial of up to one millicurie of cobalt-60. As a point source this quantity delivers a dose rate of over 100 millirems per hour at a distance of 10 centimeters. If a burial site were disturbed, and a person came into contact with one millicurie of cobalt-60 for an extended period, an overexposure could occur.

The Commission has concluded that it is inappropriate to continue generic authorization of burials pursuant to § 20.304 without regard to such factors as location of burial, concentrations of radioactive material, form of packaging, and notification of NRC. Therefore, the Commission will require that licensees obtain prior approval for new burials of the type currently allowed by § 20.304, and accordingly § 20.304 is being deleted from NRC regulations. Prior review of proposed burials will result in improved records regarding amounts and locations of future burials of radioactive material, and provide greater assurance that buried material will not present a health hazard at a later date. Thus, the risk of exposure of individuals accidentally disturbing buried radioactive waste would be reduced.

The Commission staff estimates that fewer than 100 licensees (out of about 20,000 NRC and Agreement State licensees) are performing burials allowed by § 20.304. NRC licensees will have 90 days to halt burials and apply for specific approval to resume burials pursuant to 10 CFR 20.302, or use alternative disposal methods such as transfer of waste to licensed commercial burial grounds. The NRC staff will provide information to licensees as appropriate related to obtaining approval for burials. Deletion of 10 CFR 20.304 will not affect material already buried, generally licensed and exempt material, or licensees who have already obtained specific approval to perform burials pursuant to 10 CFR 20.302.

Agreement State licensees will not be directly affected by the final rule, because they are subject to individual State regulations rather than NRC regulations. However, Agreement State officials have consistently supported deletion of § 20.304, and the Commission anticipates that those States which have not already done so will make changes in their regulations compatible with deletion of § 20.304.

As discussed in the notice of proposed rulemaking, the Commission has determined that an environmental impact statement need not be prepared because deletion of 10 CFR 20.304 will not significantly affect the quality of the human environment.

Public Comments

In reaching the decision to delete § 20.304, the Commission considered public comments received on the proposed rule change. These comments and the impact of deletion of § 20.304 are discussed in the value-impact assessment, which is available for inspection or copying for a fee at the NRC Public Document Room, 1717 H Street, Washington, D.C. 20555. The major public comments received are discussed below.

Thirty-eight sets of public comments were received on the proposed deletion of § 20.304. Seventeen commenters favored deletion, fourteen opposed deletion, and seven took no clear position. The major comments opposing deletion are: (1) Burials pursuant to § 20.304 do not represent a public health problem, (2) disposal of wastes at commercial burial grounds is not a good alternative because it is too expensive, it carriers its own risks, and the commercial sites are overburdened, and (3) NRC has not adequately outlined requirements for obtaining specific approvals for burials.

1. *Public health risk.* Several comments from institutions performing burials pursuant to § 20.304 provided information on their operations, indicating that their burial sites are safe because they are owned by the licensee, fenced and marked, located in areas of low risk of ground water contamination, or contain short-lived radionuclides in waste with low specific activity. Nevertheless, as discussed previously, the radionuclide quantities involved are potentially large enough to cause significant radiation exposures, if they are concentrated point sources, and the Commission has decided that case-by-case review of proposed burials is appropriate.

2. *Commercial burial grounds.* Many commenters incorrectly interpreted the proposed rule to mean that local burial would be prohibited, and that all waste would have to be shipped to commercial burial grounds. The Commission is not requiring that all radioactive waste affected by deletion of § 20.304 be shipped to commercial burial grounds. Licensee proposals for waste disposal will be reviewed on a case-by-case basis, including consideration of risk and economic costs. This is consistent with § 20.1(c) which provides that licensees should make every reasonable effort to maintain radiation exposures as low as is reasonably achievable, where "as low as is reasonably achievable" includes taking into account economics of improvement in relation to benefits to the public health and safety.

Several licensees performing burials pursuant to § 20.304 commented that it would be too expensive to ship wastes to commercial burial sites, and that in any case the sites are already overburdened. Estimates of the extra costs and volumes of waste involved ranged from $400 to $21,000 and 70 to 2000 cubic feet per year. It should be noted that: (1) The staff estimates that fewer than 100 licensees are performing burials pursuant to § 20.304, (2) until recently about 3,000,000 cubic feet of radioactive waste were being shipped annually to commercial sites, and (3) many institutions similar to those using § 20.304 are using commercial disposal sites. Therefore, while certain licensees may wish to dispose of high-volume, slightly contaminated waste by local burial for justifiable economic reasons, in many cases licensees could ship low-volume waste to commercial sites at reasonable cost without adding significantly to the total volume accepted at the sites.

The Commission recognizes problems associated with closures or reduced capacity of commercial burial grounds. This issue affects all licensees disposing of low-level radioactive waste, not just burials pursuant to § 20.304. The Commission staff will, of course, take into account the status of commercial burial sites in making any licensing decisions regarding disposal of radioactive waste.

3. *Criteria for disposal.* As discussed in the notice of proposed rulemaking, the Commission is reviewing existing policy on disposal of low-level radioactive waste and developing new regulations. These will be published in separate notices of proposed rulemaking. Until new regulations are developed, applications for waste disposal will be reviewed according to § 20.302, which requires licensees to submit information describing the waste material, the levels of radioactivity involved, the proposed conditions of disposal, the environment of the disposal site, and procedures to be observed to minimize the risk of unexpected or hazardous exposures.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and section 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 20, are published as a document subject to codification.

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46 FR 13971
Published 2/25/81
Effective 3/27/81

Disposal of High-Level Radioactive Wastes in Geologic Repositories: Licensing Procedures

See Part 60 Statements of Consideration

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46 FR 16230
Published 3/11/81
Effective 3/11/81

10 CFR Part 20

Biomedical Waste Disposal

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The NRC is amending its regulations to permit licensees greater leeway in disposing of liquid scintillation media and animal carcasses containing tracer levels of hydrogen-3 (tritium) or carbon-14. These rule changes will primarily affect NRC licensed hospitals and medical research institutions. Most licensees presently dispose of these items by sending them to a radioactive waste burial ground or by obtaining special authorization from NRC for incineration or onsite burial. Under the new regulations, the licensee may dispose of specified concentrations of these materials without regard to their radioactivity. The NRC is also amending its regulations to raise the annual limits for disposal of hydrogen-3 and carbon-14 by release to the sanitary sewerage systems. The rule changes will conserve waste burial capacity that is already in short supply.

EFFECTIVE DATE: March 11, 1981.

ADDRESSES: Copies of the value/impact analysis and the analysis of comments received may be examined at the Commission's Public Document Room at 1717 H Street NW., Washington, D.C. Single copies of the value/impact analysis are available from John R. Cook, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (Telephone: 301–427–4240).

FOR FURTHER INFORMATION CONTACT: John R. Cook, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (Telephone: 301–427–4240).

SUPPLEMENTARY INFORMATION:

Background

Radionuclide tracers are used extensively in biomedical research and for the diagnosis of diseases in humans. One of the end products of these research and medical activities is radioactive wastes. These wastes are usually shipped to radioactive waste burial grounds although certain water soluble or dispersible wastes are released into sanitary sewerage systems. Two of the most commonly used radionuclides in biomedical research (and to a lesser extent in medical procedures) are hydrogen-3 and carbon-14. The concentrations of these radionuclides in biomedical waste are minute, generally less than 0.05 microcuries per gram.

Liquid scintillation media and animal carcasses, both containing tracer quantities of hydrogen-3 or carbon-14, constitute the largest volume of radioactive biomedical waste.

Liquid scintillation counting has become a widespread technique for detecting radioactivity in biological samples such as blood or urine. Typically, a fraction of a milliliter of the biological sample containing tracer levels of hydrogen-3 or carbon-14 is combined with 20 milliliters or less of an organic solvent, primarily toluene, in a small vial to make a liquid scintillation medium. The vial is placed in a liquid scintillation counter, and the biological sample is assayed. The vials are used once and then collected for shipment to a radioactive waste burial ground.

Research laboratories and hospitals throughout the country presently use between 84 and 159 million vials per year, which represents between 200,000 and 400,000 gallons of liquid scintillation media. Disposal of this waste in radioactive waste burial grounds requires approximately 400,000 cubic feet of space at a cost of over $13 million per year for packing materials, transport, and disposal (this does not include the cost of licensee labor or overhead). Liquid scintillation media are approximately 43% of the total volume of radioactive waste shipped to burial grounds that is not related to industrial applications or nuclear power generation and its supporting fuel cycle.

Animals are used in research mainly for the development and testing of new drugs. Virtually every chemical compound that is considered for use as a human or veterinary drug is first tagged with a hydrogen-3 or carbon-14 tracer and injected into research animals to study how the chemical compound behaves. These research animals include mice, rats, dogs, monkeys, swine, and sheep. The animal carcasses containing tracer quantities of hydrogen-3 and carbon-14 are usually shipped to radioactive waste burial grounds. Animal carcasses annually require about 80 thousand cubic feet of burial space at a cost of almost $3 million per year. Animal carcasses are approximately 9% of the total volume of radioactive waste shipped to burial grounds that is not related to industrial applications or nuclear power generation and its supporting fuel cycle.

There are other hydrogen-3 and carbon-14 waste streams in the research laboratory that do not result in liquid scintillation vials and animal carcasses: for example, the solutions and attendant material used to prepare the research samples. These materials also contain tracer levels of hydrogen-3 and carbon-14.

Under present NRC regulations, hydrogen-3 and carbon-14 wastes that are readily soluble or dispersible in water can be disposed of by release to the sanitary sewerage systems. The annual limit for release to the sanitary sewerage systems is found in 10 CFR 20.303 and is limited to a total of 1 curie for all radionuclides per year for each licensee. Several associations of academic institutions have together asked the Radiation Policy Council to suggest that NRC raise this limit to 5 curies per year for hydrogen-3, 1 curie per year for carbon-14, and 1 curie per year for all other radionuclides. This rule amends the regulations accordingly. This change will result in a negligible addition to the level of these radionuclides already present in the natural environment.

There are alternatives for disposal of liquid scintillation media and animal carcasses containing hydrogen-3 and carbon-14 other than consignment to a radioactive waste burial ground. Liquid scintillation media can be evaporated, distilled, burned, or buried on a licensee's site if an appropriate location is available. Animal carcasses can be incinerated in a pathogen incinerator. Currently, one of these alternatives to radioactive waste burial are readily available. Generally, liquid scintillation media and animal carcasses with *any* added hydrogen-3 or carbon-14 are being handled as radioactive waste and consigned to a radioactive waste burial ground under NRC's regulations (10 CFR 30.41 and 20.301) and similar Agreement State regulations.

The state agencies that control the existing radioactive waste burial gounds do not want to accept liquid scintillation media or animal carcasses. Liquid scintillation media are flammable and are suspected of leaching other radioactive chemicals out of the burial trenches. Also, some of the shipping containers arrive at the burial grounds leaking. Liquid scintillation media are chemically toxic and are suspected of being carcinogenic and thus pose a waste hazard unrelated to their radioactive character. Animal carcasses decompose and can be a pathogen hazard. Sometimes the animal carcasses will cause their containers to burst during shipment. The voids formed in the burial trenches by the decaying animal carcasses are also believed to contribute to migration of chemicals by increasing rain water percolation in the trenches.

The three operating commercial radioactive waste burial grounds in the U.S. are located in Barnwell, South Carolina; Beatty, Nevada; and Richland, Washington. The Richland, Washington and Beatty, Nevada sites accept both liquid scintillation media and animal carcasses. However, after December 1984, the Richland, Washington site will not accept liquid scintillation media. The Barnwell, South Carolina site does not accept liquid scintillation media but does accept animal carcasses. At all three sites, the state regulatory bodies are attempting to reduce the volume of incoming waste to prolong site use.

During a temporary state-imposed embargo in mid-1979, some hospitals and research institutions across the country apparently came within days of curtailing operations involving liquid scintillation counting and animal research before the radioactive waste burial gounds in Richland, Washington and Beatty, Nevada resumed accepting liquid scintillation vials and animal carcasses.

The Rule

This final rulemaking will allow NRC licensees to dispose of liquid scintillation media and animal carcasses containing less than 0.05 microcuries of hydrogen-3 or carbon-14 per gram without regard to their radioactivity. This regulation will not relieve licensees from complying with other applicable regulations of federal, state, and local government agencies regarding the disposal of non-radioactive materials. Scintillation media are toxic and flammable, and animal carcasses are sometimes pathogenic. These characteristics, which are a more important public health problem than their radioactivity, may require them to be disposed of under applicable federal, state, and local laws governing chemical and biological hazards. This rulemaking will also allow licensees to dispose by release to sanitary sewerage systems of up to 5 curies of hydrogen-3 and 1 curie of carbon-14 per year, in addition to the presently allowed 1 curie per year for all radionuclides. Neither the rulemaking allowing disposal of liquid scintillation media and animal carcasses without regard to their radioactivity nor that raising the limit for disposal of hydrogen-3 and carbon-14 to sanitary sewerage systems, authorizes disposal of liquid scintillation media (e.g., toluene) into the sanitary sewerage systems.

The rule will essentially remove any NRC restrictions on the disposal of liquid scintillation media and animal carcasses. It will no longer be necessary for NRC licensees to ship these materials, which could pose a chemical and biological hazard, up to thousands of miles across the country for disposal in a radioactive waste burial ground. NRC Agreement States could make similar amendments to their regulations in order to extend the benefit of this action to their licensees.

The value/impact analysis prepared by the NRC staff to support the rule concludes that this rule change is the best solution to the problem of disposal of liquid scintillation media and animal carcasses containing tracer amounts of hydrogen-3 and carbon-14. If also adopted by the Agreement States, this action would save hospitals and research institutions in excess of $13 million annually ($16 million for the cost of packaging materials, transportation, and disposal, minus the $3 million estimated for non-radioactive waste disposal). Also, it will save almost one-half million cubic feet of radioactive waste burial capacity annually, or half of that used for radioactive waste not related to industrial applications or **nuclear power generation and its supporting fuel cycle.**

The value/impact analysis indicates that the action is non-substantive and insignificant from the standpoint of environmental impact. The amount of hydrogen-3 and carbon-14 that might be released to the environment each year as a result of the rule change pertaining to scintillation media and animal carcasses is small (28 curies and 6 curies respectively), particularly when compared to the steady state environmental inventory of 28 million curies of hydrogen-3 and 280 million curies of carbon-14. Calculations employing conservative assumptions indicate that if radiation exposure occurs as a result of the rule change, the maximum dose to exposed individuals is likely to be less than 1 millirem per year.

The value/impact analysis shows that highest estimated collective dose results from the assumed incineration of all 6 curies of carbon-14 contained in liquid scintillation media and animal carcasses. We calculate this release will result in a total of about 0.4 health effect during the next 1,000 generations. The average lifetime dose per person would be about 0.000001 millirem (this is a fraction of a percent of the dose and health effects attributable to natural background radiation). If incineration were to continue for the next 50 years, the average lifetime dose would be about 0.00005 millirem (for perspective, the average dose per person from a coast-to-coast airline flight is about 2.5 millirem). Further, the doses resulting from incineration of hydrogen-3 or the release to the sanitary sewerage systems of hydrogen-3 and carbon-14 are calculated to be much less than the dose from incineration of carbon-14.

In summary, the amendments concerning the disposal of tracer levels of hydrogen-3 and carbon-14 in liquid scintillation media and animal carcasses are appropriate because: (a) the amendments will not pose an unreasonable risk to the common defense and security and to the health and safety of the public; (b) disposal of these wastes in radioactive waste burial grounds is expensive and without benefit commensurate with the expense; (c) the flammability of liquid scintillation media (organic solvents) and the decomposition of animal carcasses cause a significant problem in transporting these wastes to burial grounds; and (d) these wastes consume a significant portion of radioactive waste burial capacity which is in short supply.

Similarly, the amendment raising the limit for sanitary sewerage disposal of hydrogen-3 and carbon-14 is appropriate because it will not pose an unreasonable risk to the public. In addition, the shipment of this waste to radioactive waste burial grounds is costly and consumes valuable burial space that could be made available for more hazardous radioactive waste.

The Comments

This rule was published as a proposed rule in the **Federal Register** of October 8, 1980 (45 FR 67018). The final rule is essentially the same as the proposed rule except for minor editorial changes and an additional statement regarding the non-radioactive hazardous and toxic properties of the wastes. This additional statement was included at the request of the Environmental Protection Agency and is discussed below under the heading *Fate of Wastes*. The **Federal Register** notice on the proposed rule contained essentially the same background information provided above, and invited public comments for a 45 day period ending November 24, 1980.

NRC received 321 comments on the proposed rule from academic institutions, medical facilities, state governments, professional groups, private individuals and special interest groups. Two hundred seventy one commenters supported the rule, 44 opposed it and 7 commented without indicating support or opposition. The comments supporting the rule came primarily from institutions, professional groups and individuals whose work would benefit from the rule and they cited those benefits both to their research and to society. The comments opposing the rule were split between individuals who were opposed to any release of radioactive material into the environment and individuals or special interest groups who were concerned about where this rule would lead, e.g., to a policy of dispersal of radioactive material as opposed to containment.

The comments addressed the following aspects of the proposed rule.

Need

Most of the 271 commenters who supported the rule stated their reasons. Their reasons are basically the same as those stated in the preamble to this rulemaking. The estimates of annual savings offered by the commenters if the proposed regulations went into effect ranged from $2,000–$250,000, depending on the size of the institution's biomedical program. Some of the organizations that supported the rule were the National Institutes of Health, the American Medical Association, the American College of Nuclear Physicians, the American College of Radiology, the American Hospital Association, the Joint Commission on Accreditation of Hospitals, the Society of Nuclear Medicine, the Endocrine Society, the American Council on Education, Scientists for Public Safety and the Intersociety Council for Biology and Medicine.

A few of the opposing comments questioned the need for the rulemaking. One of these commenters asked, "If there were no space problems, would the question of changing the regulations ever have arisen?"

The answer to this question is, yes, the regulations need changing even without the problem of space in the burial grounds because present regulations impose an economic and administrative burden on licensees that is not justified. As one commenter who favored the proposed rule observed:

> "* * * My own experience is that the strict regulations now in effect have resulted in the holding of hundreds of dead carcasses until money becomes available for proper packaging of these materials for disposal. The result has been a significant reduction in research and a reluctance to undertake projects which involve low levels of radioactivity in animals. Thus, my experience indicates that present restrictions have inhibited research * * *"

There are additional reasons for the rule changes regarding safety at the burial grounds, transportation to the burial grounds and safety in the laboratory. The problems in shipping these wastes to the burial grounds and the problems that these wastes cause in the burial trenches are discussed above under *Background*. Regarding safety in the laboratory, one commenter favoring the regulation observed:

> "I believe the effort expended in meeting previous regulations has been more damaging to the health of my laboratory personnel than the small amount of radiation, i.e., difficulties of lung and skin exposure to toluene-based fluids (despite the use of hoods, gloves, etc.). I hope these hazards will decrease with these rules."

Scope

While one-third of the commenters supporting the rule urged NRC to expand the scope of the rule to include other hydrogen-3 and carbon-14 waste streams or to include other radionuclides in various waste streams, several of the commenters opposing the rule urged NRC to abandon the rule because it might lead to other rulemakings identifying further waste streams or radionuclides as candidates for disposal without regard to their radioactivity. These latter comments most often cited the need for a comprehensive environmental analysis covering all possible radionuclides and all possible waste streams as their reason for opposing this present rulemaking.

The Commission is aware of the merit of having one comprehensive rulemaking to include many or perhaps all of the possible radionuclides and waste streams. This type of comprehensive rulemaking and its associated generic environmental analysis of all of the benefits and risks is theoretically an optimum approach, but as a practical matter it is an unworkable approach. The practical approach is to examine the specific waste streams which contribute a large volume to the burial grounds as candidates for alternative regulatory approaches. The U.S. Radiation Policy Council at their September 25, 1980 public meeting discussed both the generic approach and the specific waste streams approach. At that meeting the Council:

> "Adopted a Federal policy acknowledging that there are concentrations of specific radionuclides in specific waste streams which pose such small risks that control for radiation protection purposes is not necessary. In accordance with this policy requested that the NRC present to the (Council's) Working Group by November 18 an interim plan for identification and analysis of specific waste streams beginning with the C–14 and H–3 (tritium) medical waste streams for which early action is appropriate and develop a proposed regulatory framework for this activity."

Single copies of that interim plan, called for by the Council, are available from John R. Cook at the above address.

Fate of Wastes

Several commenters, both for and against the proposed rule, expressed concern about the fate of these biomedical wastes if the NRC allowed disposal without regard to their radioactivity. Most of these commenters were concerned that the liquid scintillation medium toluene, which is flammable and toxic, would be poured down the drain and into the sanitary sewerage systems. The Environmental Protection Agency (EPA), while supporting NRC's amendment covering liquid scintillation media and animal carcasses, recommended that the regulation itself include a clarifying statement that disposal of scintillation media and animal carcasses without regard to their radioactivity will not relieve licensees from complying with other applicable regulations of federal, state and local government agencies regarding chemical and biological hazards. This recommendation was echoed by two other commenters. Also, a group of sanitation workers expressed concern that they might face an increased occupational hazard from the radioactive wastes, which they believed might concentrate in certain sewerage system components.

The preambles to both the proposed rule and this final rule include a statement similar to that recommended by EPA and others. However, the Commission agrees with EPA and those commenters who would like to see such a clarifying statement in the regulation itself regarding the non-radioactive hazards of liquid scintillation media and animal carcasses. Therefore, a statement has been added to the final rule at 10 CFR 20.306(d) as follows:

> "(d) Nothing in this section relieves the licensee from complying with other applicable federal, state, and local regulations governing any other toxic or hazardous property of these materials."

Finally, regarding the question of a radiation hazard to sanitation workers from deposition in sewerage system components, because the hydrogen-3 and carbon-14 behave chemically the same as non-radioactive hydrogen and carbon, there is no reason to expect significant deposition or accumulation in sewerage system components. Further, hydrogen-3 and carbon-14 emit weak beta radiations, which are completely shielded by piping, conduit, ground, water, etc.

Concentration Limit

A few commenters questioned the concentration limit in the proposed rule which was set at 0.05 microcuries or less of hydrogen-3 or carbon-14, per gram of liquid scintillation medium or animal tissue. Some commenters simply asked about the basis for the 0.05 microcuries per gram value. One commenter said the concentration limit should be raised to 0.1–0.2 microcuries per gram. Another commenter said that the concentration limit should be lowered to 0.02 or 0.025 microcuries per gram.

The commenter who suggested raising the concentration limit said that this could be done on the basis of the analysis of risks due to releases at these levels. The commenter who suggested lowering the proposed concentration limit offered an analysis which shows that 0.05 microcuries per gram is too high an activity for liquid scintillation counting and that 0.02 microcuries per gram will cover most applications of liquid scintillation counting. This latter commenter pointed out that the "as low as is reasonably achievable" (ALARA) concept of radiation protection dictates going to the lower concentration limit. This same commenter argued for an overall release limit for each licensee based on his analysis which assumes that all of the 200,000–400,000 gallons of liquid scintillation media are released at the maximum 0.05 microcuries per gram level.

The 0.05 microcuries per gram concentration limit was recommended to the Commission by its expert consultants as a level that would cover most biomedical research involving tracer use in animals. The Commission adopted the same level for liquid scintillation media as an administrative simplification, recognizing that the 0.05 microcuries per gram level will be higher than that normally encountered in liquid scintillation work. If the limit were set much closer to the concentrations actually used, licensees would be required to perform more exacting calculations and analytical steps to demonstrate compliance with the rule. This adds to the cost of administration for both the licensees and NRC. Setting the concentration limit at 0.05 microcuries per gram for both animal carcasses and liquid scintillation media does not violate the ALARA principle because the concentrations actually used are controlled by the sensitivity of the counting equipment and the cost of hydrogen-3 and carbon-14 labelled compounds which typically are quite expensive.

The Commission derived its estimates of the potential quantities of hydrogen-3 and carbon-14 released to the environment as a result of this rulemaking from actual production and use data. It would be erroneous to assume that all of the liquid scintillation media would be released at the maximum 0.05 microcuries per gram concentration. This assumption leads to release estimates that exceed the total produced for such uses.

Basically, the value/impact analysis does not indicate the need for a maximum release limit for each licensee. The Commission does not believe that setting the concentration limit higher than that actually used in practice will result in unnecessary (non-ALARA) releases to the environment. The Commission does believe that these higher limits will reduce the cost of administration of these regulations.

Value/Impact Analysis

Several commenters both for and against the proposed rule commented on the preliminary value/impact analysis. A few commenters suggested that the final value/impact analysis consider the impact of multiple users on a common sewerage system disposing of hydrogen-3 and carbon-14 under the new limits. Also, the Environmental Protection Agency recommended lower dilution factors for this part of the analysis. The Commission agrees with these comments and the final value/impact analysis addresses the impact of multiple users and employs adjusted dilution factors. The conclusion of the analysis, however, has not changed, i.e., the amendment raising the limit for sanitary sewerage disposal of hydrogen-3 and carbon-14 is appropriate because it will not pose an unreasonable risk to the public.

The Environmental Protection Agency and at least one other commenter observed that the information presented in the preliminary value/impact analysis was not sufficient to support the need to raise the limits for hydrogen-3 and carbon-14 which can be discharged to sanitary sewers. The EPA also stated that the increased health risk from the release of hydrogen-3 and carbon-14 in the quantities now in use appears to be very low.

The Commission believes that raising the limits for release of hydrogen-3 and carbon-14 to the sanitary sewerage systems will benefit perhaps 20–30 NRC licensees. The dollar savings in radioactive waste burial capacity are not known; however, even some savings in the cost of medical research and some savings in radioactive waste burial capacity are a direct benefit to the public and should not be foregone because they are difficult to quantify.

Finally, the Environmental Protection Agency noted that the preliminary value/impact analysis gave estimates of the individual doses which might result from the proposed changes; however, they suggested that the final value/impact analysis include an assessment of the collective dose commitment. The preliminary value/impact analysis included a brief treatment of the collective dose commitment. The final value/impact analysis includes a more rigorous treatment of this question. However, the conclusion of the final value/impact analysis has not changed. Basically, the value/impact analysis concludes this rulemaking is non-substantive and insignificant from the standpoint of environmental impact.

Clarifications

Several commenters requested clarification on the boundaries of the rule change. Does the term liquid scintillation media include the vials containing the media? Does the term animal tissue include organs or fluids which may have been removed from the carcasses for analysis?

The regulation in 10 CFR 20.306(a) applies to the disposal of liquid scintillation media of 0.05 microcuries or less of hydrogen-3 or carbon-14 per gram of medium. Licensees may dispose of liquid scintillation media containing this concentration of hydrogen-3 or carbon-14 without regard to its radioactivity. Scintillation vials themselves are not radioactive. Rather, it is the scintillation media remaining in the vials that contains the radioactivity. The rule covers that material. Therefore, it would be permissible to dispose of the used vials along with the media.

Similarly, the regulation in 10 CFR 20.306(b) applies to the disposal of animal tissue of 0.05 microcuries or less of hydrogen-3 or carbon-14 per gram of tissue *averaged over the weight of the entire animal*, whether the tissue (or organ) is ultimately removed from the carcass or not. However, the regulation does not apply to either the radioactive chemicals before they are administered to the animals or to the animal feces or urine or contaminated bedding.

Finally, some commenters asked if the rule change would permit incineration of the scintillation media and animal carcasses without obtaining permission from NRC via a license amendment. The answer is, yes, liquid scintillation media and animal carcasses may be incinerated without a license amendment to the extent permitted by applicable non-radioactive waste disposal regulations.

This rule is being made effective on March 11, 1981, because it relieves licensees from restrictions.

Authority: Under the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and Sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 20, are published as a document subject to codification.

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46 FR 18525
Published 3/25/81
Effective dates for the existing
requirement to comply with
EPA's 40 CFR Part 190 are
already specified in
40 CFR 190.12:
12/1/79 for most operations;
12/1/80 for uranium mills; and
1/1/83 for discharges of
krypton-85 and iodine-129.
Effective date for these
amendments to 10 CFR
Part 20 is 6/23/81.

10 CFR Part 20

Environmental Radiation Protection Standards for Nuclear Power Operations

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations to incorporate the existing Environmental Protection Agency requirement for certain uranium fuel cycle licensees to comply with the EPA's "Environmental Radiation Protection Standards for Nuclear Power Operations". These standards require certain uranium fuel cycle facilities to be operated such that releases of radioactive materials and resulting radiation doses to the public are below specified limits. The amendments also require licensees to submit reports to NRC when those standards have been or may be exceeded.

EFFECTIVE DATES: The effective dates for the existing requirement to comply with EPA's 40 CFR Part 190 are already specified in 40 CFR 190.12: December 1, 1979 for most operations; December 1, 1980 for uranium mills; and January 1, 1983 for discharges of krypton-85 and iodine-129. The effective date for these amendments to 10 CFR Part 20 is June 23, 1981.

FOR FURTHER INFORMATION CONTACT: Mr. John W. N. Hickey, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (phone: (301) 443-5966).

SUPPLEMENTARY INFORMATION: The Nuclear Regulatory Commission (NRC) is amending its regulations in 10 CFR Part 20, "Standards for Protection Against Radiation," to incorporate the existing Environmental Protection Agency (EPA) requirement for compliance with 40 CFR Part 190, "Environmental Radiation Protection Standards for Nuclear Power Operations." The EPA published 40 CFR Part 190 on January 13, 1977 (42 FR 2858). In accordance with a Memorandum of Understanding between EPA and the former Atomic Energy Commission (38 FR 24936, September 11, 1973), NRC is responsible for enforcing the provisions of 40 CFR Part 190 for NRC licensees.

Title 40 CFR Part 190 requires certain uranium fuel cycle facilities to be operated so that releases of radioactive material and resulting radiation doses to the public are below specified limits. The effective dates for compliance are December 1, 1979 for most operations; December 1, 1980 for uranium mills; and January 1, 1983 for discharges of krypton-85 and iodine-129. The regulation provides that under certain circumstances variances may be granted by the regulatory agency responsible for enforcing 40 CFR Part 190.

The amendments to NRC regulations state that NRC licensees must comply with 40 CFR Part 190, and require licensees to submit reports to NRC when 40 CFR Part 190 limits have been or may be violated.

The NRC has submitted these amendments to the Comptroller General for such review as may be appropriate under the Federal Reports Act, as amended, 44 U.S.C. 3512. The date on which the reporting requirement of this rule becomes effective reflects inclusion of the 45-day period which that statute allows for such review (44 U.S.C. 3513(c)(2)).

As discussed in the notice of proposed rulemaking, the Commission has concluded that an environmental impact statement for the amendments is not required, because they will not significantly affect the quality of the human environment.

The amendments were published for public comment on April 17, 1980 (45 FR 26072), with comments requested by June 16, 1980. Timely comments were received from Northeast Utilities, Duke Power Company, Consumers Power Company, and the County of San Diego. The public comments are available for free inspection or copying for a fee at the NRC Public Document Room, 1717 H Street, Washington, D.C. 20555. No significant adverse comments or questions were received on the proposed amendments during the public comment period.[1] Therefore, they are being published in final form with only one minor change. Following is a discussion of the issues raised by the public comments.

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[1] In October, 1980 approximately four months after the comment period closed, several operators of uranium mills jointly filed later comments on this proposed rule. They basically requested the Commission to defer implementation of the NRC program to enforce Part 190 at uranium mills. Recognizing that their comments were late, these operators requested in the alternative that their filing be treated as a petition to rescind any NRC regulations imposing Part 190 requirements on uranium mills. In a separate action, the American Mining Congress also moved the Commission in October, 1980 to stay implementation and enforcement of Part 190 at NRC licensed uranium mills. The Commission is currently considering these filings. However, the issuance of these amendments as a final rule needs not be delayed. For the most part, these amendments simply incorporate into 10 CFR Part 20 the NRC's already existing responsibility to enforce 40 CFR Part 190 at fuel cycle facilities including uranium mills. Issuance of these amendments as a final rule does not modify that responsibility. Thus, because these amendments do not change the status quo regarding the Commission's authority, they can be issued before the Commission reaches a decision on pending requests to delay enforcement of Part 190.

1. One comment stated that the amendments were unnecessary because licensees are already required to comply with 40 CFR Part 190. The purpose of the amendments is to incorporate the existing 40 CFR Part 190 requirements into NRC regulations to make it more clear that compliance with 40 CFR Part 190 is required.

2. One comment stated that the requirements of 40 CFR Part 190 and 10 CFR Part 50 Appendix I should be combined, because both regulations relate to radioactive releases from nuclear power reactors. This is not practical because 40 CFR Part 190 also applies to fuel cycle facilities other than power reactors, and because the two regulations are not identical. However, whenever possible, the NRC staff is avoiding unnecessary duplicative requirements for reactors by combining release limits and reporting requirements for 40 CFR Part 190 with existing Appendix I requirements in individual licensees' technical specifications.

3. One comment expressed concern that 40 CFR Part 190 applied to combined radiation doses from all fuel cycle facilities, making it difficult to determine compliance. EPA addressed this issue when 40 CFR Part 190 was published. EPA stated: "* * * in the vast majority of situations, the sum of all reasonably postulable contributions from sources other than the immediate site will be small compared to these standards and should be ignored in assessing compliance" (42 FR 2858, January 13, 1977).

4. One comment pointed out that 40 CFR Part 190 allows for licensees to obtain variances to exceed 40 CFR Part 190 limits under temporary and unusual conditions, and requested NRC to specify procedures for obtaining such variances. Because variances will be considered only in unusual cases, it is preferable to treat each case on an individual basis. This is consistent with existing NRC regulations, which do not specify procedures for obtaining variances to exceed regulatory limits. Rather, 10 CFR § 20.501 states, "The Commission may, upon application by any licensee or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not result in undue hazard to life or property."

One minor clarifying change related to variances was made to the proposed rule. When a licensee submits to NRC a report of excessive radioactive releases, the description of corrective steps taken or planned shall include the schedule for achieving conformance with 40 CFR Part 190 and associated license conditions. This is consistent with 40 CFR 190.11, which requires that a regulatory agency granting a variance should make public the schedule for achieving conformance with 40 CFR Part 190.

5. One comment stated that licensees should have 60 days to report violations of 40 CFR Part 190 to NRC, rather than the 30 days specified in the proposed rule. The reason given was that licensees need more time to perform calculations associated with assessing compliance. The NRC staff has concluded that the 30-day requirement is reasonable. Specific license conditions which implement this requirement for individual facilities will allow reasonable time to gather data and perform dose calculations as appropriate.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and section 553 of title 5 of the United States Code, the following amendments are published as a document subject to codification.

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46 FR 53647
Published 10/30/81
Effective 11/30/81

10 CFR Part 20

Radiation Protection Survey Requirement; Miscellaneous Clarifying Amendments

AGENCY: Nuclear Regulatory Commission

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) has revised its regulations to make clear that, in accordance with the original regulatory intent, persons may be cited for violation of the NRC radiation protection survey requirement in § 20.201(b) for failure to perform surveys when indicated or for performing inadequate surveys. Persons may be cited not only when the failure to survey or the performance of an inadequate survey results in a violation of another NRC radiation protection standard but also in those circumstances in which violation of an NRC radiation protection standard could have occurred because of the lack of an adequate survey even though no such additional violation actually did occur.

EFFECTIVE DATE: November 30, 1981.

FOR FURTHER INFORMATION CONTACT: Alan K. Roecklein, Occupational Radiation Protection Branch, Office of Nuclear Regulatory Research USNRC, Washington, D.C. 20555, Telephone (301) 443-5970.

SUPPLEMENTARY INFORMATION: On July 3, 1980, the Nuclear Regulatory Commission (NRC) published in the Federal Register (45 FR 45302–45303) proposed miscellaneous clarifying amendments to §§ 20.101, 20.103, 20.104(a), (b), 20.105 and 20.201(b) of its "Standards for Protection Against Radiation" in 10 CFR Part 20. Interested persons were invited to submit written comments and suggestions on the proposed amendments during the sixty-day comment period which expired September 2, 1980. Five letters of comment were received. While all the commenters addressed the proposed changes to §§ 20.101, 20.103, 20.104(a), (b) and 20.105, only one commenter expressed views on the proposed clarifying amendment to § 20.201(b).

After reviewing the public comments, the NRC has decided that it would be best to consider the proposed clarifying amendments to §§ 20.101, 20.103, 20.104(a), (b) and 20.105 in connection with the overall review and revision of 10 CFR Part 20 currently in progress (45 FR 18023, March 20, 1980, Standards for Protection Against Radiation; Advance Notice of Proposed Rulemaking). These miscellaneous clarifying amendments will accordingly be considered in that proceeding and resolved in a manner appropriate to and consistent with the proposed overall revision of Part 20. For this reason, the NRC is not responding to the public comments on §§ 20.101, 20.103, 20.104(a), (b) and 20.105 at the present time. Instead, the NRC will address these comments in connection with the major revision of Part 20.

Since the need for a clarifying amendment to the survey requirement in § 20.201(b) remains pressing and since this change is readily separable from the other clarifying amendments contained in the July 3, 1980, notice of proposed rulemaking, the NRC has decided, in the interest of protecting the public health and safety, to promulgate a clarifying amendment to § 20.201(b) at this time.

The only public comment received on the proposed clarifying amendment to 10 CFR 20.201(b) questioned whether the proposed language eliminated the goal of preventing overexposures. The proposed rule was not intended to eliminate preventive actions because tho objective and principal function of the survey requirement is preventive. By providing information concerning the extent of radiation and radioactive material hazards that may be present, the survey serves as an effective tool in preventing both the occurrence of violations of 10 CFR Part 20 and the development of conditions in which violations of 10 CFR Part 20 could occur.

Arguments by some licensees that the text of § 20.201(b) lends support to the view that § 20.201(b) is enforceable only when noncompliance with the survey requirement results in violation of another Part 20 requirement provided the impetus for the proposed change. For example, one licensee argued that § 20.201 was not violated where a person entered a radiation field of 2000 rem/hr after performing an inaccurate and incomplete survey indicating a radiation field of 70 rem/hr and did not receive an exposure in excess of Part 20 limits. However, the sole commenter suggested that a change of § 20.201(b) was not essential to eliminate inadequate surveying that might cause but did not actually result in additional violations because the present language in § 20.201(b) could be read to cover such circumstances. The Commission continues to believe that § 20.201(b) should be clarified to make clear to all concerned that in order to provide adequate protection of worker health and safety, each licensee has an independent and enforceable obligation to ascertain the extent of radiation hazards present by conducting adequate surveys. This amendment puts licensees on notice that compliance with the Commission's radiological requirements in Part 20 should be by design and not fortuitous

While there is a significant relationship between the survey requirement and other Part 20 requirements, in that information obtained through responsible compliance with § 20.201(b) may well prove essential in determining whether a licensee has or has not satisfied other Part 20 requirements, this is not the primary function of the survey requirement. The principal role of the survey requirement is preventive. Adequate survey procedures provide measurable protection for the health and safety of the worker and the public because they provide the information necessary for the establishment of adequate protective measures. The usefulness of this "early warning system" may be seriously reduced if licensees are not held responsible for failure to conduct any survey or for failure to conduct an adequate survey when violations of other Part 20 requirements have not occurred. Therefore, to make enforcement of the survey requirement, § 20.201(b) contingent upon whether other violations of Part 20 have in fact occurred, may adversely impact the survey purpose of preventing potential harm to the worker or the public.

Although there has been no change in the purpose of the clarifying amendment, the text of revised § 20.201(b) differs from the text set out in the proposed rule. As suggested by the commenter, the existing text of § 20.201(b) has been retained with an addition to make clear that surveys must be reasonably intended to prevent violations. The clarifying phrase provides that when a violation of other Part 20 requirements has not occurred, the Commission will consider in determining whether § 20.201 survey requirement has met the reasonableness of the actions taken in the light of all the circumstances to evaluate the extent of radiation hazards.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and Sections 552 and 553 of Title 5 of the United States Code, the following clarifying amendment to 10 CFR Part 20 is published as a document subject to codification

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46 FR 57665
Published 11/25/81
Effective 11/25/81

10 CFR Parts 1 and 20

Change of Address for NRC Region V Office

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule; change of address.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations to change the address for NRC's Region V office located in Walnut Creek, California. The amendments are necessary to inform the public of the new address for NRC Region V.

EFFECTIVE DATE: November 25, 1981.

FOR FURTHER INFORMATION CONTACT: J. M. Felton, Director, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Telephone (301) 492-7211.

SUPPLEMENTARY INFORMATION: The Nuclear Regulatory Commission has relocated its Region V office in Walnut Creek, California. The new address for the Region V office is 1450 Maria Lane, Suite 210, Walnut Creek, California 94596.

The amendments are made to § 1.3(b) and Appendix D to Part 20. The amendment to Appendix D to Part 20 is made as a complete revision of the appendix in order to simplify its format.

The amendment necessary to reflect the relocation of Region V in Appendix A to Part 73 is made in a document upgrading notification procedures for reporting events that significantly affect physical security effectiveness.

Since these amendments are administrative and relate solely to a minor procedural matter, notice of proposed rulemaking and public procedure thereon are unnecessary, and good cause exists to make the amendments effective November 25, 1981.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations are published as a document subject to codification.

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46 FR 58281
Published 12/1/81
Effective 12/1/81

Licensing Requirements for the Storage of Spent Fuel in an Independent Spent Fuel Storage Installation; Minor Clarifying and Conforming Amendments

See Part 72 Statements of Consideration

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47 FR 16162
Published 4/15/82
Effective 4/15/82
Correction 47 FR 19511

10 CFR Part 20

Standards for Protection Against Radiation; Replacement of Provisions of Regulatory Guide 8.15

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations, "Standards for Protection Against Radiation," 10 CFR Part 20, to place requirements for an acceptable respiratory protection program, currently incorporated by reference in § 20.103, directly into § 20.103. This is a minor non-policy amendment to the regulation in response to denial by the Office of the Federal Register of continued approval of that incorporation-by-reference provision.

EFFECTIVE DATE: April 15, 1982.

FOR FURTHER INFORMATION CONTACT: Ms. Lynnette Hendricks, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (301) 443-5970.

SUPPLEMENTARY INFORMATION: On November 9, 1981, the Nuclear Regulatory Commission published for comment in the **Federal Register** (46 FR 55271) a proposed amendment to 10 CFR Part 20 of its regulations. Existing paragraph 20.103(c) of 10 CFR Part 20 states that "when respiratory protective equipment is used to limit the inhalation of airborne radioactive material * * *, the licensee may make allowance for such use in estimating exposures of individuals to such materials provided that such equipment is used as stipulated in Regulatory Guide 8.15, 'Acceptable Programs for Respiratory Protection.[6]'"

Footnote 6 then states that, "This incorporation by reference provision was approved by the Director of the Federal Register on October 19, 1976 * * *" The Office of the Federal Register will no longer allow material published in a Regulatory Guide to be incorporated into the regulations by reference, and has given the Nuclear Regulatory Commission until March 1, 1982, to take alternative action.

Regulatory Guide 8.15 contains procedural and technical provisions for an acceptable program, including bioassay, air sampling, specifications for high efficiency filters and the quality of breathing air in supplied-air devices, to list a few, which are being incorporated directly into the regulations. A "table of protection factors" in the guide sets forth the amount of allowance permitted for certain types of respiratory protection devices. This table is being incorporated in Appendix A to Part 20 and will reflect several corrections previously made in the table by a Bulletin and a Information Notice issued by the NRC Office of Inspection and Enforcement. These changes were that a protection factor for hoods of 2000 is allowed only if the air flow to the wearer is supplied at the manufacturer's recommended maximum pressure/flow rate. A protection factor of no more than 1000 is allowed for these devices operated at the minimum pressure/air flow-rate of 6 cubic feet per minute. The protection factors for atmosphere-supplying respirators were reduced from 50 and 10 for full and half-mask respirators respectively operating in demand mode to 5 for both types of masks. A new category of respiratory protection devices was added under self-contained breathing apparatus. This is a positive pressure, recirculating device (rebreather), designated RP with a protection factor of 5000 allowed if the specified conditions are met. The first two of these changes were made previously by a Bulletin issued by the Nuclear Regulatory Commission's Office of Inspection and Enforcement on June 12, 1978, and the later change by an Information Notice issued on August 28, 1981 (IN–81–26), also by the Nuclear Regulatory Commission's Office of Inspection and Enforcement.

Three errors in the proposed rule were noted by NRC staff and commenters. These errors were corrected as follows:

1. Under Category I, "Air-Purifying Respirators," the third entry should have read: "Facepiece, half-mask, full or hood".

The "full" was mistakenly omitted in the proposed rule.

2. Under Category II, "Atmosphere-Supplying Respirators," the 2nd and 4th entry were changed from 10 and 50 to 5, but the explanation of the change was not included in the Supplementary Information section of the proposed rule. The protection factors for full and half-mask respirators with this type of device, operated in the demand mode, were reduced from 10 for half masks and 50 for full facepiece masks to 5 for both types pursuant to the NRC Office of Inspection and Enforcement Bulletin No. 78–07, June 12, 1978. The Bulletin was issued on the basis of a Los Alamos National Laboratory study performed for NRC which indicated that much of this type of equipment does not achieve a protection factor greater than 5.

3. The 2nd entry under Part 2, "Self-contained breathing apparatus" of Category II was mistakenly listed as 2000 instead of 10,000. The Office of the Federal Register printed a correction for this error in the **Federal Register** on December 8, 1981 (46 FR 60005).

Seven clarifying changes were made in response to public comments on the transfer of requirements from Regulatory Guide 8.15 to § 20.103 and Appendix A of Part 20. Four changes were made as a result of a comment stating that the rule change was substantive and not just administrative in nature due to the omission of certain requirements that were in Regulatory Guide 8.15. In response to that comment:

1. Section 20.103(c)(3) was added to read as follows:

> A written policy statement on respirator usage shall be issued covering such things as: use of practicable engineering controls instead of respirators; routine, nonroutine, and emergency use of respirators; and periods of respirator use and relief from respirator use. The licensee shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other condition that might require such relief.

2. Section 20.103(c)(4) was added to read as follows:

> The licensee uses equipment within limitations for type and mode of use and provides proper visual, communication, and other special capabilities (such as adequate skin protection) when needed.

3. The following was added to footnote (i) pertaining to supplied-air suits:

> There shall be a standby rescue person equipped with self-contained breathing apparatus and communications equipment whenever supplied-air suits are used.

4. A statement was added to § 20.103(c)(2) requiring written procedures for testing of respirators for operability immediately prior to each use.

A change was made in response to a commenter noting that the requirement for correcting exposure records when estimates are greater than the corrected value places a huge professional and bookkeeping burden on the licensee since actual protection factors afforded by respirators vary from day to day for the same individual, and protection factors are generally much higher than allowed in the table of protection factors. In addition, a number of work groups are chronically exposed to low concentrations of airborne radioactive materials which further complicates calculation of accurate dose assessments for the many tasks performed by these workers. In response to this comment the last sentence in § 20.103(c)(1) was modified to read:

> "If the exposure is later found to be greater than estimated, the corrected value shall be used; if the exposure is later found to be less than estimated, the corrected value *may* be used" (emphasis added).

Two clarifying changes suggested by a commenter were made on the new entry in the table of protection factors, Appendix A, positive pressure rebreathers, designated RP, pursuant to the intent of NRC Office of Inspection and Enforcement Information Notice, IN–81–26, August 1981. These changes are as follows:

1. The description of positive pressure rebreathers was changed from pressure-demand (PD) to positive pressure (PP). The term positive pressure is technically more correct because the device operates on continuous flow versus demand from a regulator, as do the pressure demand, open circuit devices.

2. Footnote (l)* on rebreathers, positive pressure, has been modified to state that service life is substantially reduced on all positive pressure, self-contained devices if the device is not properly fitted to the wearer's face. The commenter noted that the service life of all positive pressure self-contained breathing apparatus, not just the rebreathers or closed circuit type, is reduced substantially when perceptible

*Correction 47 FR 19511

outward leakage of gas is detected around the mask. Footnote (l)* changed to acknowledge this fact.

Section 20.103, paragraph (d) stating that the Commission may impose further restrictions (1) on the use of respirators rather than process, containment, ventilation, or other engineering controls, and (2) as might be necessary to assure that the respiratory protective program of the licensee is adequate to limit exposure of personnel to airborne radioactive materials, is being deleted. Although that section of the regulations was promulgated in 1976, there has seldom if ever been an occasion to use it. However, if a need arose to restrict the use of respirators beyond what is otherwise stated in the regulations, the Commission has that authority anyway and would deal with those situations on a case-by-case basis.

Because the amendments set forth below relate to a minor, administrative change and because of the Office of the Federal Register's March 1, 1982, deadline for this rule change, the NRC has found that good cause exists for making the rule effective upon publication without the customary 30-day waiting period.

Paperwork Reduction Act Statement

Requirements exist in this rule change for: Written procedures for selection, fitting, and maintenance of respirators, and testing of respirators for operability immediately prior to each use; written procedures regarding supervision and training of personnel and issuance records; and a determination by a physician prior to initial use of respirators, and at least every 12 months thereafter, that the individual wearing respiratory protective equipment is physically capable of wearing the equipment. These requirements have been approved by the Office of Management and Budget pursuant to the Paperwork Reduction Act, Pub. L. 96–511, Approval No. 3150–0014.

Regulatory Flexibility Statement

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), it is hereby certified that this rule will not have a significant economic impact upon a substantial number of small entities. This rule change incorporates into the Commission's regulations requirements for an "acceptable" respiratory protection program that were previously incorporated by reference in Regulatory Guide 8.15.

The only licensees identified as having established "acceptable" respiratory protection programs in accordance with 10 CFR 20.103 are power reactor licensees, uranium milling licensees, fuel fabrication facility licensees, and large radiopharmaceutical companies. These licensees do not fall within the definition of a small business found in the Small Business Size Standards regulations issued at 13 CFR Part 121 by the Small Business Administration, or in section 3 of the Small Business Act, 15 U.S.C. 632, or the definition of a "small entity" at section 601(3) of the Regulatory Flexibility Act.

List of Subjects in 10 CFR Part 20

Byproduct material, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Penalty, Radiation protection, Reporting requirements, Special nuclear material, Source material, and Waste treatment and disposal.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 20 are published as a document subject to codification.

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47 FR 19511
Published 5/6/82

10 CFR Part 20

Standards for Protection Against Radiation; Replacement of Provisions of Regulatory Guide 8.15

Correction

In FR Doc. 82–10366, appearing at page 16162 in the issue for Thursday, April 15, 1982, please make the following corrections:

(1) On page 16163, in the third column, in the last paragraph, in the first line, the reference to "Footnote (1)" (one), should have read "Footnote (l)" ("ell").

(2) On page 16164, in the first column, in the second line, the reference to "Footnote (1)" (one), should have read "Footnote (l)" ("ell").

(3) On page 16165, in Appendix A, under the table, in footnote $^{4-1}$, the formula should have read:

$$\text{Concentration inhaled} = \frac{\text{Ambient airborne concentration}}{\text{Protection factor}}$$

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47 FR 41336
Published 9/20/82
Effective 9/20/82

Minor Clarifying Amendments

See Part 1 Statements of Consideration

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47 FR 57446
Published 12/27/82
Effective dates:
10 CFR 20.311 of Part 20 effective date is 12/27/83; 10 CFR Part 61 and all other changes effective 1/26/83.

Licensing Requirements for Land Disposal of Radioactive Waste

See Part 61 Statements of Consideration

≫ 48 FR 33850
Published 7/26/83
Effective 1/1/84

10 CFR Parts 20 and 50

Licensee Event Report System

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Commission is amending its regulations to require the reporting of operational experience at nuclear power plants by establishing the Licensee Event Report (LER) system. The final rule is needed to codify the LER reporting requirements in order to establish a single set of requirements that apply to all operating nuclear power plants. The final rule applies only to licensees of commercial nuclear power plants. The final rule will change the requirements that define the events and situations that must be reported, and will define the information that must be provided in each report.

EFFECTIVE DATE: January 1, 1984. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of January 1, 1984.

FOR FURTHER INFORMATION CONTACT: Frederick J. Hebdon, Chief, Program Technology Branch, Office for Analysis and Evaluation of Operational Data, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555; Telephone (301) 492–4480.

SUPPLEMENTARY INFORMATION:

I. Background

On May 6, 1982, the NRC published in the **Federal Register** (47 FR 19543)[1] a Notice of Proposed Rulemaking that would modify and codify the existing Licensee Event Report (LER) system. Interested persons were invited to submit written comments to the Secretary of the Commission by July 6, 1982. Numerous comments were received. After consideration of the comments and other factors involved, the Commission has amended the proposed requirements published for public comment by clarifying the scope and content of the requirements, particularly the criteria that define which operational events must be reported.

The majority of the comments on the proposed rule: (1) Questioned the meaning and intent of the criteria that defined the events which must be reported, (2) questioned the need for reporting certain specific types of events, and (3) questioned the need for certain information that would be required to be included in an LER. Section III of this notice discusses the comments in more detail.

II. Rulemaking initiation

The Nuclear Plant Reliability Data (NPRD) system is a voluntary program for the reporting of reliability data by nuclear power plant licensees. On January 30, 1980 (45 FR 6793),[1] the NRC published an Advance Notice of Proposed Rulemaking that described the NPRD system and invited public comment on an NRC plan to make it mandatory. Forty-four letters were received in response to the advanced notice. These comments generally opposed making the NPRD system mandatory on the grounds that reporting of reliability data should not be made a regulatory requirement.

In December 1980, the Commission decided that the requirements for reporting of operational experience data needed major revision and approved the development of an Integrated Operational Experience Reporting (IOER) system. The IOER system would have combined, modified, and made mandatory the existing Licensee Event Report (LER) system and the NPRD system. SECY 80–507[1] discusses the IOER system.

As a result of the Commission's approval of the concept of an IOER system, the NRC published another advance notice on January 15, 1981 (46 FR 3541). This advance notice explained why the NRC needed operational experience data and described the deficiencies in the existing LER and NPRD systems.

On June 8, 1981, the Institute of Nuclear Power Operations (INPO) announced that because of its role as an active user of NPRDs data it would assume responsibility for management and funding of the NPRD system. Further, INPO decided to develop criteria that would be used in its management audits of member utilities to assess the adequacy of participation in the NPRD system.

The two principal deficiencies that had previously made the NPRD system an inadequate source of reliability data were the inability of its committee management structure to provide the necessary technical direction and a low level of participation by the utilities. The commitments and actions by INPO provided a basis for confidence that these two deficiencies would be corrected. For example, centralizing the management and funding of NPRDS within INPO should overcome the previous difficulties associated with management by a committee and funding from several independent organizations. Further, with INPO focusing upon a utility's participation in NPRDS as a specific evaluation parameter during routine management and plant audit activities, the level of utility participation, and therefore, the quality and quantity of NPRDS data, should significantly increase. However, the Commission will continue to have an active role in NPRDS by participating in an NPRDS User's Group, by periodically assessing the quality and quantity of information available from NPRDS, and by auditing the timely availability of the information to the NRC.

Since there was a likelihood that NPRDS under INPO direction would meet the NRC's need for reliability data, it was no longer necessary to proceed with the IOERS. Hence, the collection of detailed technical descriptions of significant events could be addressed in a separate rulemaking to modify and codify the existing LER reporting requirements. See SECY 81–494 for additional details concerning IOERS.

However, the Commission wishes to make it explicitly clear that it is relaxing the reporting requirements with the expectation that sufficient utility participation, cooperation, and support of the NPRD system will be forthcoming. If the NPRD system does not become operational at a satisfactory level in a reasonable time, remedial action by the Commission in the form of additional rulemaking may become necessary.

On October 6, 1981, the NRC published an advanced notice (46 FR 49134) that deferred development of the IOER system and sought public comment on the scope and content of the LER system. Six comment letters were received in response to this ANPRM. All of the comments received were reviewed by the staff and were considered in the development of the proposed LER rule. See SECY 82–3 [1] for additional details.

This rule identifies the types of reactor events and problems that are believed to be significant and useful to the NRC in its effort to identify and resolve threats to public safety. It is designed to provide the information necessary for engineering studies of operational anomalies and trends and patterns analysis of operational occurrences. The same information can also be used for other analytic procedures that will aid in identifying accident precursors.

The Commission believes that the NRC should continue to seek an improved operational data system that will maximize the value of operational data. The system should encompass and integrate operational data of events and problem sequences identified in this rule, NPRDS data, and such other information as is required for a comprehensive integrated analytically-versatile system.

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[1] Copies of the documents are available for public inspection and copying for a fee at the Public Document Room at 1717 H Street NW. Washington, D.C.

The Brookhaven Study, published as BNL/NUREG 51609, NUREG/CR 3206, discusses data collection and storage procedures to support multivariate, multicase analysis. While the range of reactor configurations in the U.S. nuclear industry presents some methodological and interpretative problems, these difficulties should not be insurmountable. The Commission believes that the NRC should have as a specific objective the development, demonstration, and implementation of an integrated system for collecting and analyzing operational data that will employ the predictive and analytical potential of multicase, multivariate analyses. Accordingly, the staff has been directed to undertake the work necessary to develop and demonstrate such a cost-effective integrated system of operational data collection and analyses.

If the design of the system demonstrates that such a system is feasible and cost-effective, development of the system to the point of initiating rule should be completed by July 1986.

III. Analysis of Comments

The Commission received forty-seven (47) letters commenting on the proposed rule. Copies of those letters and a detailed analysis of the comments are available for public inspection and copying for a fee at the NRC Public Document Room at 1717 H Street, NW., Washington, D.C. A number of the more substantive issues are discussed below.

Licensee Resources

Of particular concern to the Commission was the impact that the proposed rule would have on the resources used by licensees to prepare LERs. The Commission's goal was to assure that the scope of the rule would not increase the overall level of effort above that currently required to comply with the existing LER requirements. Thirty letters of the 47 received contained comments on the overall acceptability of the proposed rule or commented directly on the question of scope and/or resources associated with the proposed rule. The views of the commenters can be characterized as follows:

1. Five commenters felt that the scope and level of effort would be greatly expanded by the proposed rule. Estimates included an increase of 100 man-years for the entire industry, an increase of three times the current effort, and an increase of $100,000 and 2 man-years annually for each plant.

2. Four commenters felt that the level of effort would be increased but not significantly.

3. One commenter felt that the proposed rule would have a minimal effect on the level of effort required.

4. Two commenters felt that the proposed rule would significantly reduce the number of LERs filed.

5. Thirteen commenters endorsed the objective of improving LER reporting but felt that changes in the proposed rule were needed. These commenters did not directly address the resource issue.

6. Five commenters endorsed the proposed rule and/or felt that it was a significant improvement over the existing reporting requirements.

Based on these comments and its own assessment of the impact of this rule, the Commission has concluded that the impact of this rule will be no greater than the impact of the existing LER requirements, and this rule will not place an unacceptable burden on the affected licensees.

Relationship Between the LER Rule (§ 50.73) and the Immediate Notification Rule (§ 50.72)

As a parallel activity to the preparation of § 50.73, the Commission is amending its regulations (§ 50.72) which require that licensees for nuclear power plants notify the NRC Operations Center of significant events that occur at their plants. On December 21, 1981, the Commission published in the **Federal Register** a proposed rule (46 FR 61894) that described the planned changes in § 50.72.

The **Federal Register** notice accompanying the proposed LER rule (i.e., § 50.73) stated that additional changes anticipated to § 50.72 would be made but they would be "* * * largely administrative and the revised § 50.72 would not be significantly modified nor would it be published again for public comment." Several commenters disagreed with this conclusion.

The commenters did, however, agree with the Commission's position that inconsistencies and overlapping requirements between the two rules need to be eliminated.

The Commission has carefully reviewed the proposed requirements in the LER and Immediate Notification rules and has concluded that although changes to both have been made (largely in response to public comments) to clarify the intent of the rules, the original intent and scope have not been significantly changed. Therefore, the Commission has concluded that these two rules need not be published again for public comment.

Engineering Judgment

In the **Federal Register** notice that accompanied the proposed rule, the Commission stated that licensee's engineering judgment may be used to decide if an event is reportable. Several commenters expressed the belief that some wording should be added to the rule of reflect that the NRC will also use judgment in enforcement of this regulation where the licensee is requested to use engineering judgment.

The Commission believes that the LER rule adequately discusses the need for and application of the concept of "engineering judgment." The concept itself includes the recognition of the existence of a reasonable range of interpretation regarding this rule, and consequently the Commission recognizes and hereby acknowledges the need for flexibility in enforcement actions associated with this rule. The Commission believes that this concept is sufficiently clear and that additional explicit guidance is not necessary.

Reporting Schedule

In the **Federal Register** notice that accompanied the proposed rule, the Commission stated that it had not yet decided if the reports should be submitted in fifteen days or thirty days following discovery of a reportable event. Many commenters stated that the time frame for reporting LERs should not be less than thirty days after the discovery of a reportable event.

One commenter estimated the impact of a requirement to submit a report sooner than 30 days following discovery of a reportable event would be an increase of approximately 40 man years per year for the currently operating plants. In addition the commenter estimated that if a summary report were also required the reporting burden would increase an additional 12 man years for the currently operating plants.

In response to these comments, the Commission has decided to require that LERs be submitted within 30 days of discovery of a reportable event or situation.

Reporting of Reactor Trips

Section 50.73(a)(1) of the proposed rule (§ 50.73(a)(2)(iv) of the final rule) required reporting of any event which results in an unplanned manual or automatic actuation of any Engineered Safety Feature (ESF) including the Reactor Protection System (RPS). Many commenters agreed that these events should be trended and analyzed, but disagreed that they deserve to be singled out as events of special significance (i.e., events reportable as

LERs). They noted that reports of RPS actuations are already reported to the NRC in the Monthly Operating Status Report, as well as telephoned to the NRC Operations Center.

In addition, the Institute of Nuclear Power Operations (INPO) analyzed the frequency of reactor scrams during a one-month period. This analysis indicated that an average of 55 reactor trips would be reportable each month under the proposed rule. INPO equated this to 660 additional LERs per year for all currently operating plants, or approximately 32 man-years of additional effort for all the currently operating plants based upon the assumption that each LER requires 100 man-hours of effort to prepare and analyze.

The Commission still believes that ESF actuations, including reactor trips, frequently are associated with significant plant transients and are indicative of events that are of safety significance. In addition, if the ESFs are being challenged during routine transients, that fact is of safety significance and should be reported.

In addition, the Commission does not agree with the estimate that each LER submitted for a routine reactor trip would require, on the average, 100 man-hours to prepare and analyze. Licensees are already required to make internal evaluation of and document significant events, including reactor trips. Therefore, the incremental impact of preparing and analyzing the LER should be significantly less than 100-man hours. In addition, the actual increase in burden would be offset by reductions in the burden of reporting less significant events that would no longer be reportable.

Coordination With Other Reporting Requirements

Several commenters noted that the proposed rule did not appear to be coordinated with other existing reporting requirements, and that duplication of licensee effort might result. They recommended that LER reporting be consolidated to eliminate potential duplication of other existing reporting requirements.

The Commission has reviewed existing NRC reporting requirements (e.g., 10 CFR Parts 20 and 21, § 50.55(e), § 50.72, § 50.73, § 73.71, and NUREG–0654) and has attempted, to the extent practicable, to eliminate redundant reporting and to ensure that the various reporting requirements are consistent. Many of the changes in the final LER rule are as a result of this effort. These changes resulted in extensive revisions in the wording of criteria contained in this rule, but did not change the original scope of intent of the requirements. In addition, in order to make the requirements in §§ 50.72 and 50.73 more compatible, the order (i.e., numbering) of the criteria in § 50.73 has been changed. The changes are noted in the discussion of each paragraph below.

Finally, conforming amendments are being made to various sections of Parts 20 and 50 in order to reduce the redundancy in reporting requirements that apply to operating nuclear power plants. In general, these amendments will require that:

1. Licensees that have an Emergency Notification System (ENS) make the reports required by the subject sections via the ENS. All other licensees will continue to make the reports to the Administrator of the appropriate NRC Regional Office.
2. Written reports required by the subject sections be submitted to the NRC Document Control Desk in Washington, D.C., with a copy to the appropriate Regional Offices.
3. Holders of licenses to operate a nuclear power plant submit the written reports required by the subject sections in accordance with the procedures described in § 50.73(b).

The criteria contained in the subject sections which define a reportable event have not been modified.

Similar changes are also planned as part of curent activities to make more substantive changes to Part 21, § 50.55(e), and § 73.71.

Nonconservative Interdependence

Several commenters expressed difficulty in understanding the meaning of the phrase "nonconservative interdependence" as used in the proposed § 50.73(a)(3). The wording of § 50.73(a)(3) (§ 50.73(a)(2)(vii) of this final rule) has been changed to eliminate the phrase "non conservative interdependence" by specifically defining the types of events that should be reported. The revised paragraph does not, however, change the intent of the original paragraph.

Sabotage and Threats of Violence

Several commenters noted that the security-related reporting requirements of § 50.73(a)(6) (§ 50.73(a)(2)(iii) of this final rule)) were already contained in greater detail in 10 CFR 73.71. For instance, § 73.71 requires an act of sabotage to be reported immediately, followed by a written report within 15 days. The proposed rule would have required an LER to be filed within 30 days. Although distribution of reports is somewhat different, redundant reporting would have occurred. The commenters recommended that the Commission ensure consistency between §§ 50.73 and 73.71.

In response to these comments the Commission has deleted the reporting of sabotage and threats of violence from § 50.73 because these situations are adequately covered by the reporting requirements contained in § 73.71.

Evacuation of Rooms or Buildings

Many commenters stated that the reporting of in-plant releases of radioactivity that require evacuation of individual rooms (§ 50.73(a)(7) in the proposed rule or (§ 50.73(a)(2)(x) of this final rule) was inconsistent with the general thrust of the rule to require reporting of significant events. They noted that minor spills, small gaseous waste releases, or the disturbance of contaminated particulate matter (e.g., dust) may all require the temporary evacuation of individual rooms until the airborne concentrations decrease or until respiratory protection devices are utilized. They noted that these events are fairly common and should not be reportable unless the required evacuation affects the entire facility or a major portion thereof.

In response to these comments the wording of this criterion (§ 50.73(a)(2)(x) in the final rule) has been changed to significantly narrow the scope of the criterion to include only those events which significantly hamper the ability of site personnel to perform safety-related activities (e.g., evacuation of the main control room).

Energy Industry Identification System

Many commenters noted that the requirement to report the Energy Industry Identification System (EIIS) component function identifier and system name of each component or system referred to in the LER description would be a significant burden on the licensee.

They suggested instead that the NPRDS component identifiers be used in place of the EIIS component identifiers which are not yet widely used by the industry.

The Commission continues to believe that EIIS system names and component function identifiers are needed in order that LERs from different plants can be compared. We do not, however, suggest that the EIIS identifiers be used throughout the plant, but only that they be added to the LER as it is written. A simple, inexpensive table could be used to translate plant identifiers into equivalent EIIS identifiers.

The Commission considered the system and component identifiers used in NPRDS as an alternative. It is our understanding, however, the NPRDS will soon adopt the EIIS system titles, so a distinction should no longer exist. In addition, LERs frequently include systems that are not included in the scope of NPRDS (i.e., an NPRDS system identification does not exist) while EIIS, on the other hand, includes all of the systems commonly found in commercial nuclear power plants. Further, NPRDS includes only 39 component identifiers (e.g., valve, pump). The Commission believes that this limited number does not provide a sufficiently detailed description of the component function involved.

Function of Failed Components and Status of Redundant Components

Many commenters said that information required in (§ 50.73(b)(2) (vi) and (vii) of the proposed rule should not be a requirement in the LER. They argued that this information is readily available in documents previously submitted to the NRC by licensees and are available for reference.

The final rule (§ 50.73(b)(2)(i)(G)) has been modified to narrow the scope of the information requested by the Commission.

While this general information may be available in licensee documents previously submitted to the NRC, the Commission believes that a general understanding of the event and its significance should be possible without reference to additional documentation which may not be readily or widely available, particularly to the public.

The Commission continues to believe that the licensee should prepare an LER in sufficient depth so that knowledgeable readers who are conversant with the design of commercial nuclear power plants, but are not familiar with the details of a particular plant, can understand the general characteristics of the event (e.g., the cause, the significance, the corrective action). As suggested by the commenters, more detailed information to support engineering evaluations and case studies will be obtained, as needed, directly from the previously submitted licensee documents.

Engineering Evaluations

The overview discussion of the proposed rule contains the following statement: "If the NRC staff decides that the event was especially significant from the standpoint of safety, the staff may request that the licensee perform an engineering evaluation of the event and describe the results of that evaluation."

Several commenters argued that the inclusion of the requirement that the licensee perform an engineering evaluation of certain events at the staff's request appeared unjustified and would add substantially to the burden of reporting. They argued that the licensee should be required to submit only the specific additional information required for the necessary engineering evaluation rather than to perform the evaluation.

The rule has been modified to require only the submittal of any necessary additional information requested by the Commission in writing.

IV. Specific Findings

Overview of the LER System

When this final LER rule becomes effective, the LER will be a detailed narrative description of potentially significant safety events. By describing in detail the event and the planned corrective action, it will provide the basis for the careful study of events or conditions that might lead to serious accidents. If the NRC staff decides that the event was especially significant from the standpoint of safety, the staff may request that the licensee provide additional information and data associated with the event.

The licensee will prepare an LER for those events or conditions that meet one or more of the criteria contained in § 50.73(a). The criteria are based primarily on the nature, course, and consequences of the event. Therefore, the final LER rule requires that events which meet the criteria are to be reported regardless of the plant operating mode or power level, and regardless of the safety significance of the components, systems, or structures involved. In trying to develop criteria for the identification of events reportable as LERs, the Commission has concentrated on the potential consequences of the event as the measure of significance. Therefore, the reporting criteria, in general, do not specifically address classes of initiating events or causes of the event. For example, there is no requirement that all personnel errors be reported. However, many reportable events will involve or have been initiated by personnel errors.

Finally, it should be noted that licensees are permitted and encouraged to report any event that does not meet the criteria contained in § 50.73(a), if the licensee believes that the event might be of safety significance, or of generic interest or concern. Reporting requirements aside, assurance of safe operation of all plants depends on accurate and complete reporting by each licensee of all events having potential safety significance.

Paragraph-by-Paragraph Explanation of the LER Rule

The significant provisions of the final LER rule are explained below. The explanation follows the order in the proposed rule.

Paragraph 50.73(a)(2)(iv) (proposed paragraph 50.73(a)(1)) requires reporting of: "Any event or condition that resulted in manual or automatic actuation of any Engineered Safety Feature (ESF), including the Reactor Protection System (RPS). However, actuation of an ESF, including the RPS, that resulted from and was part of the preplanned sequence during testing or reactor operation need not be reported."

This paragraph requires events to be reported whenever an ESF actuates either manually or automatically, regardless of plant status. It is based on the premise that the ESFs are provided to mitigate the consequences of a significant event and, therefore: (1) They should work properly when called upon, and (2) they should not be challenged frequently or unnecessarily. The Commission is interested both in events where an ESF was needed to mitigate the consequences (whether or not the equipment performed properly) and events where an ESF operated unnecessarily.

"Actuation" of multichannel ESF Actuation Systems is defined as actuation of enough channels to complete the minimum actuation logic (i.e., activation of sufficient channels to cause activation of the ESF Actuation System). Therefore, single channel actuations, whether caused by failures or otherwise, are not reportable if they do not complete the minimum actuation logic.

Operation of an ESF as part of a planned operational procedure or test (e.g., startup testing) need not be reported. However, if during the planned operating procedure or test, the ESF actuates in a way that is not part of the planned procedure, that actuation must be reported. For example, if the normal reactor shutdown procedure requires that the control rods be inserted by a manual reactor trip, the reactor trip need not be reported. However, if conditions develop during the shutdown that require an automatic reactor trip, such a reactor trip must be reported.

The fact that the safety analysis assumes that an ESF will actuate automatically during certain plant conditions does not eliminate the need to report that actuation. Actuations that need not be reported are those initiated for reasons other than to mitigate the consequences of an event (e.g., at the discretion of the licensee as part of a planned procedure or evolution).

Sections 50.73(a)(2) (v) and (vi) (proposed § 50.73(a)(2)) require reporting of:

* * * * *

> (v) Any event or condition that alone could have prevented the fulfillment of the safety function of structures or systems that are needed to:
>
> (A) Shut down the reactor and maintain it in a safe shutdown condition;
>
> (B) Remove residual heat;
>
> (C) Control the release of radioactive material; or
>
> (D) Mitigate the consequences of an accident.
>
> (vi) Events covered in paragraph (a)(2)(v) of this section may include one or more personnel errors, equipment failures, and/or discovery of design, analysis, fabrication, construction, and/or procedural inadequacies. However, individual component failures need not be reported pursuant to this paragraph if redundant equipment in the same system was operable and available to perform the required safety function.

The wording of this paragraph has been changed from the proposed rule to make it easier to read. The intent and scope of the paragraph have not been changed.

The intent of this paragraph is to capture those events where there would have been a failure of a safety system to properly complete a safety function, regardless of when the failures were discovered or whether the system was needed at the time.

This paragraph is also based on the assumption that safety-related systems and structures are intended to mitigate the consequences of an accident. While § 50.73(a)(2)(iv) of this final rule applies to actual actuations of an ESF, § 50.73(a)(2)(v) of this final rule covers an event or condition where redundant structures, components, or trains of a safety system could have failed to perform their intended function because of: one or more personnel errors, including procedure violations; equipment failures; or design, analysis, fabrication, construction, or procedural deficiencies. The event must be reported regardless of the situation or condition that caused the structure or systems to be unavailable, and regardless of whether or not an alternate safety system could have been used to perform the safety function (e.g., High Pressure Core Cooling failed, but feed-and-bleed or Low Pressure Core Cooling were available to provide the safety function of core cooling).

The applicability of this paragraph includes those safety systems designed to mitigate the consequences of an accident (e.g., containment isolation, emergency filtration). Hence, minor operational events involving a specific component such as valve packing leaks, which could be considerd a lack of control of radioactive material, should not be reported under this paragraph. System leaks or other similar events may, however, be reportable under other paragraphs.

It should be noted that there are a limited number of single-train systems that perform safety functions (e.g., the High Pressure Coolant Injection System in BWRs). For such systems, loss of the single train would prevent the fulfillment of the safety function of that system and, therefore, must be reported even though the plant Technical Specifications may allow such a condition to exist for a specified limited length of time.

It should also be noted that, if a potentially serious human error is made that could have prevented fulfillment of a safety function, but recovery factors resulted in the error being corrected, the error is still reportable.

The Commission recognizes that the application of this and other paragraphs of this section involves the use of engineering judgment on the part of licensees. In this case, a technical judgment must be made whether a failure or operator action that did actually disable one train of a safety system, could have, but did not, affect a redundant train within the ESF system. If so, this would constitute an event that "could have prevented" the fulfillment of a safety function, and, accordingly, must be reported.

If a component fails by an apparently random mechanism it may or may not be reportable if the functionally redundant component could fail by the same mechanism. Reporting is required if the failure constitutes a condition where there is reasonable doubt that the functionally redundant train or channel would remain operational until it completed its safety function or is repaired. For example, if a pump in one train of an ESF system fails because of improper lubrication, and engineering judgment indicates that there is a reasonable expectation that the functionally redundant pump in the other train, which was also improperly lubricated, would have also failed before it completed its safety function, then the actual failure is reportable and the potential failure of the functionally redundant pump must be discussed in the LER.

For safety systems that include three or more trains, the failure of two or more trains should be reported if, in the judgement of the licensee, the functional capability of the overall system was jeopardized.

Interaction between systems, particularly a safety system and a non-safety system, is also included in this criterion. For example, the Commission is increasingly concerned about the effect of a loss or degradation of what had been assumed to be non-essential inputs to safety systems. Therefore, this paragraph also includes those cases where a service (e.g., heating, ventilation, and cooling) or input (e.g., compressed air) which is necessary for reliable or long-term operation of a safety system is lost or degraded. Such loss or degradation is reportable if the proper fulfillment of the safety function is not cannot be assured. Failures that affect inputs or services to systems that have no safety function need not be reported.

Finally the Commission recognizes that the licensee may also use engineering judgment to decide when personnel actions *could* have prevented fulfillment of a safety function. For example, when an individual improperly operates or maintains a component, he might conceivably have made the same error for all of the functionally redundant components (e.g., if he incorrectly calibrates one bistable amplifier in the Reactor Protection System, he could conceivably incorrectly calibrate all bistable amplifiers). However, for an event to be reportable it is necessary that the actions actually affect or involve components in more than one train or channel of a safety system, and the result of the actions must be undesirable from the perspective of protecting the health and safety of the public. The components can be functionally redundant (e.g., two pumps in different trains) or not functionally redundant (e.g., the operator correctly stops a pump in Train "A" and, instead of shutting the pump discharge valve in Train "A," he mistakenly shuts the pump discharge valve in Train "B").

Section 50.73(a)(2)(vii) (proposed § 50.73(a)(3)) requires the reporting of: "Any event where a single cause or condition caused at least one independent train or channel to become inoperable in multiple systems or two independent trains channels or to become inoperable in a system designed to:

(A) Shut down the reactor and maintain it in a safe shutdown condition,

(B) Remove residual heat,

(C) Control the release of radioactive material; or

(D) Mitigate the consequences of an accident."

This paragraph has been changed to clarify the intent of the phrase "nonconservative interdependence." Numerous comment letters expressed difficulty in understanding what this phrase meant; so the paragraph has been changed to be more specific. The new paragraph is narrower in scope than the original paragraph because the term is specifically defined, but the basic intent is the same.

This paragraph requires those events to be reported where a single cause produced a component or group of components to become inoperable in redundant or independent portions (i.e., trains or channels) of one or more systems having a safety function. These events can identify previously unrecognized common cause failures and systems interactions. Such failures can be simultaneous failures which occur because of a single initiating cause (i.e., the single cause or mechanism serves as a common input to the failures); or the failures can be sequential (i.e., cascade failures), such as the case where a single component failure results in the failure of one or more additional components.

To be reportable, however, the event or failure must result in or involve the failure of independent portions of more than one train or channel in the same or different systems. For example, if a cause or condition caused components in Train "A" and "B" of a single system to become inoperable, even if additional trains (e.g., Train "C") were still available, the event must be reported. In addition, if the cause or condition caused components in Train "A" of one system and in Train "B" of another system (i.e., a train that is assumed in the safety analysis to be independent) to become inoperable, the event must be reported. However, if a cause or condition caused components in Train "A" of one system and Train "A" of another system (i.e., trains that are not assumed in the safety analysis to be independent), the event need not be reported unless it meets one or more of the other criteria in this section.

In addition, this paragraph does not include those cases where one train of a system or a component was removed from service as part of a planned evolution, in accordance with an approved procedure, and in accordance with the plant's Technical Specifications. For example, if the licensee removes part of a system from service to perform maintenance, and the Technical Specifications permit the resulting configuration, and the system or component is returned to service within the time limit specified in the Technical Specifications, the action need not be reported under this paragraph. However, if, while the train or component is out of service, the licensee identifies a condition that could have prevented the whole system from performing its intended function (e.g., the licensee finds a set of relays that is wired incorrectly), that condition must be reported.

Section 50.73(a)(2)(i) (proposed § 50.73(a)(4)) requires reporting of:

"(A) The completion of any nuclear plant shutdown required by the plant's Technical Specifications; or

"(B) Any operation prohibited by the plant's Technical Specifications; or

"(C) Any deviation from the plant's Technical Specifications authorized pursuant to § 50.54(x) of this part."

This paragraph has been reworded to more clearly define the events that must be reported. In addition, the scope has been changed to require the reporting of events or conditions "prohibited by the plant's Technical Specifications" rather than events where "a plant Technical Specification Action Statement is not met." This change accommodates plants that do not have requirements that are specifically defined as Action Statements.

This paragraph now requires events to be reported where the licensee is required to shut down the plant because the requirements of the Technical Specifications were not met. For the purpose of this paragraph, "shutdown" is defined as the point in time where the Technical Specifications require that the plant be in the first shutdown condition required by a Limiting Condition for Operation (e.g., hot standby (Mode 3) for PWRs with the Standard Technical Specifications). If the condition is corrected before the time limit for being shut down (i.e., before completion of the shutdown), the event need not be reported.

In addition, if a condition that was prohibited by the Technical Specifications existed for a period of time longer than that permitted by the Technical Specifications, it must be reported even if the condition was not discovered until after the allowable time had elapsed and the condition was rectified immediately after discovery.

Section 50.73(a)(2)(ii) (proposed § 50.73(a)(5)) requires reporting of: "Any event or condition that resulted in the condition of the nuclear power plant, including its principal safety barriers, being seriously degraded, or that resulted in the nuclear power plant being:

"(A) In an unanalyzed condition that significantly compromised plant safety;

"(B) In a condition that was outside the design basis of the plant; or

"(C) In a condition not covered by the plant's operating and emergency procedures."

This paragraph requires events to be reported where the plant, including its principal safety barriers, was seriously degraded or in an unanalyzed condition.

For example, small voids in systems designed to remove heat from the reactor core which have been previously shown through analysis not to be safety significant need not be reported. However, the accumulation of voids that could inhibit the ability to adequately remove heat from the reactor core, particularly under natural circulation conditions, would constitute an unanalyzed condition and must be reported. In addition, voiding in instrument lines that results in an erroneous indication causing the operator to significantly misunderstand the true condition of the plant is also an unanalyzed condition and must be reported.

The Commission recognizes that the licensee may use engineering judgment and experience to determine whether an unanalyzed condition existed. It is not intended that this paragraph apply to minor variations in individual parameters, or to problems concerning single pieces of equipment. For example, at any time, one or more safety-related components may be out of service due to testing, maintenance, or a fault that has not yet been repaired. Any trivial single failure or minor error in performing surveillance tests could produce a situation in which two or more often unrelated, safety-related components are out-of-service. Technically, this is an unanalyzed condition. However, these events should be reported only if they involve functionally related components or if they significantly compromise plant safety.

Finally, this paragraph also includes material (e.g., metallurgical, chemical) problems that cause abnormal degradation of the principal safety barriers (i.e., the fuel cladding, reactor coolant system pressure boundary, or the containment).

Additional examples of situations included in this paragraph are:

(a) Fuel cladding failures in the reactor or in the storage pool, that exceed expected values, that are unique or widespread, or that resulted from unexpected factors.

(b) Reactor coolant radioactivity levels that exceeded Technical Specification limits for iodine spikes or, radioactivity levels at a BWR air ejector monitor that exceeded the Technical Specification limits.

(c) Cracks and breaks in piping, the reactor vessel, or major components in the primary coolant circuit that have safety relevance (steam generators, reactor coolant pumps, valves, etc.)

(d) Significant welding or material defects in the primary coolant system.

(e) Serious temperature or pressure transients (e.g., transients that violate the plant's Technical Specifications).

(f) Loss of relief and/or safety valve operability during test or operation (such that the number of operable valves or man-way closures is less than required by the Technical Specifications).

(g) Loss of containment function or integrity (e.g., containment leakage rates exceeding the authorized limits).

Section 50.73(a)(2)(iii) (proposed § 50.73(a)(6)) requires reporting of: "Any natural phenomenon or other external condition that posed an actual threat to the safety of the nuclear power plant or significantly hampered site personnel in the performance of duties necessary for the safe operation of the nuclear power plant."

This paragraph has been reworded to make it clear that it applies only to acts of nature (e.g., tornadoes) and external hazards (e.g., railroad tank car explosion). References to acts of sabotage have been removed because they are covered by § 73.71. In addition, threats to personnel from internal hazards (e.g., radioactivity releases) are now covered by a separate paragraph (§ 50.73(a)(2)(x)).

This paragraph requires those events to be reported where there is an actual threat to the plant from an external condition or natural phenomenon, and where the threat or damage challenges the ability of the plant to continue to operate in a safe manner (including the orderly shutdown and maintenance of shutdown conditions).

The licensee is to decide if a phenomenon or condition actually threatened the plant. For example, a minor brush fire in a remote area of the site that was quickly controlled by fire fighting personnel and, as a result, did not present a threat to the plant need not be reported. However, a major forest fire, large-scale flood, or major earthquake that presents a clear threat to the plant must be reported. Industrial or transportation accidents that occurred near the site and created a plant safety concern must also be reported.

Section 50.73(a)(2)(x) (proposed § 50.73(a)(7)) requires reporting of: "Any event that posed an actual threat to the safety of the nuclear power plant or significantly hampered site personnel in the performance of duties necessary for the safe operation of the nuclear power plant including fires, toxic gas releases, or radioactive releases."

This paragraph has been reworded to include physical hazards (internal to the plant) to personnel (e.g., electrical fires). In addition, in response to numerous comments, the scope has been narrowed so that the hazard must hamper the ability of site personnel to perform safety-related activities affecting plant safety.

In-plant releases must be reported if they require evacuation of rooms or buildings containing systems important to safety and, as a result, the ability of the operators to perform necessary safety functions is significantly hampered. Precautionary evacuations of rooms and buildings that subsequent evaluation determines were not required need not be reported.

Proposed § 50.73(a)(8) was intended to capture an event that involved a controlled release of a significant amount of radioactive material to offsite areas. In addition, "significant" was based on the plant's Technical Specification limits for the release of radioactive material. However, this section has been deleted because the reporting of these events is already required by § 50.73(a)(2)(i) and § 20.405.

Section 50.73(a)(2) (viii) and (ix) (proposed § 50.73(a)(9)) require reporting of:

* * * * *

(viii)(A) Any airborne radioactivity release that exceeded 2 times the applicable concentrations of the limits specified in Table II of Appendix B to Part 20 of this chapter in unrestricted areas, when averaged over a time period of one hour.

(B) Any liquid effluent release that exceeded 2 times the limiting combined Maximum Permissible Concentration (MPC) (see Note 1 of Appendix B to Part 20 of this chapter) at the point of entry into the receiving water (i.e., unrestricted area) for all radionuclides except tritium and dissolved noble gases, when averaged over a time period of one hour.

(ix) Reports submitted to the Commission in accordance with paragraph (a)(2)(viii) of this section also meet the effluent release reporting requirements of paragraph 20.405(a)(5) of Part 20 of this chapter.

* * * * *

Paragraph (viii) has been changed to clarify the requirements to report releases of radioactive material. The paragraph is similar to § 20.405 but places a lower threshold for reporting events at commercial power reactors. The lower threshold is based on the significance of the breakdown of the licensee's program necessary to have a release of this size, rather than on the significance of the impact of the actual release.

Reports of events covered by § 50.73(a)(2)(viii) are to be made in lieu of reporting noble gas releases that exceed 10 times the instantaneous release rate, without averaging over a time period, as implied by the requirement of § 20.405(a)(5).

Paragraph 50.73(b) describes the format and content of the LER. It requires that the licensee prepare the LER in sufficient depth so that knowledgeable readers conversant with the design of commercial nuclear power plants, but not familiar with the details of a particular plant, can understand the complete event (i.e., the cause of the event, the plant status before the event, and the sequence of occurrences during the event).

Paragraph 50.73(b)(1) requires that the licensee provide a brief abstract describing the major occurrences during the event, including all actual component or system failures that contributed to the event, all relevant operator errors or violations of procedures, and any significant corrective action taken or planned as a result of the event. This paragraph is needed to give LER data base users a brief description of the event in order to identify events of interest.

Paragraph 50.73(b)(2) requires that the licensee include in the LER a clear, specific narrative statement of exactly what happened during the entire event so that readers not familiar with the details of a particular plant can understand the event. The licensee should emphasize how systems, components, and operating personnel performed. Specific hardware problems should not be covered in excessive detail. Characteristics of a plant that are unique and that influenced the event (favorably or unfavorably) must be described. The narrative must also describe the event from the perspective of the operator (e.g., what the operator saw, did, perceived, understood, or misunderstood).

Paragraph 50.73(b)(3) requires that the LER include a summary assessment of the actual and potential safety consequences and implications of the event. This assessment may be based on the conditions existing at the time of the event. The evaluation must be carried out to the extent necessary to fully assess the safety consequences and safety margins associated with the event. An assessment of the event under alternative conditions must be included if the incident would have been more severe (e.g., the plant would have been in a condition not analyzed in the Safety Analysis Report) under reasonable and credible alternative conditions, such as power level or operating mode. For example, if an event occurred while the plant was at 15% power and the same event could have occurred while the plant was at 100% power, and, as a result, the consequences would have been considerably more serious, the licensee must assess and report those consequences.

Paragraph 50.73(b)(4) requires that the licensee describe in the LER any corrective actions planned as a result of the event that are known at the time the LER is submitted, including actions to reduce the probability of similar events occurring in the future. After the initial LER is submitted only substantial changes in the corrective action need be reported as a supplemental LER.

Paragraph 50.73(c) authorizes the NRC staff to require the licensee to submit specific supplemental information beyond that required by § 50.73(b). Such information may be required if the staff finds that supplemental material is necessary for complete understanding of an unusually complex or significant event. Such requests for supplemental information must be made in writing, and the licensee must submit the requested information as a supplement to the initial LER within a time period mutually agreed upon by the NRC staff and the licensee.

Paragraph 50.73(f) gives the NRC's Executive Director for Operations the authority to grant case-by-case exemptions to the reporting requirements contained in the LER system. This exemption could be used to limit the collection of certain data in those cases where full participation would be unduly difficult because of a plant's unique design or circumstances.

Paragraph 50.73(g) states that the reporting requirements contained in § 50.73 replace the reporting requirements in all nuclear power plant Technical Specifications that are typically associated with Reportable Occurrences.

The reporting requirements superseded by § 50.73 are those contained in the Technical Specification sections that are usually titled "Prompt Notification with Written Followup" (Section 6.9.1.8) and "Thirty Day Written Reports" (Section 6.9.1.9). The reporting requirements that have been superseded are also described in Regulatory Guide 1.16, Revision 4, "Reporting of Operating Information–Appendix A Technical Specification," Paragraph 2, "Reportable Occurrences." The special report typically described in Section 6.9.2 "Special Reports" of the Technical Specifications are still required.

V. Regulatory Analysis

The Commission has prepared a regulatory analysis for this final rule. The analysis examines the costs and benefits of the alternatives considered by the Commission. A copy of the regulatory analysis is available for inspection and copying for a fee at the NRC Public Document Room, 1717 H Street, N.W., Washington, D.C. Single copies of the analysis may be obtained from Frederick J. Hebon, Chief, Program Technology Branch, Office for Analysis and Evaluation of Operational Data, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555; Telephone (301) 492–4480.

VI. Paperwork Reduction Act Statement

The Nuclear Regulatory Commission has submitted this rule to the Office of Management and Budget for such review as may be appropriate under the Paperwork Reduction Act, Pub. L. 96–511. The date on which the reporting requirements of this rule become effective reflects inclusion of the 60-day period which the Act allows for such review.

VII. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission hereby certifies that this rule will not have a significant economic impact on a substantial number of small entities. This final rule affects electric utilities that are dominant in their respective service areas and that own and operate nuclear utilization facilities licensed under sections 103 and 104b of the Atomic Energy Act of 1954, as amended. The amendments clarify and modify presently existing notification requirements.

Accordingly, there is no new, significant economic impact on these licensees, nor do these licensees fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the Small Business Size Standards set out in regulations issued by the Small Business Administration at 13 CFR Part 121.

List of Subjects

10 CFR Part 20

Licensed material, Nuclear power plants and reactors, Penalty, Reporting and recordkeeping requirements.

10 CFR PARTS 50

Incorporation by reference, Antitrust, Classified information, Fire protection, Intergovernmental relations, Nuclear power plants and reactors, Penalty, Radiation protection, Reporting and recordkeeping requirements.

Under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552 and 553, the following amendments to 10 CFR Parts 20 and 50 are published as a document subject to codification.

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48 FR 38604
Published 8/25/83
Effective 8/22/83

10 CFR Parts 20, 21, and 73

Minor Clarifying Amendments

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to indicate a change in the commercial telephone number for the NRC's Region III Office. The amendments are necessary to inform the public of these administrative changes to NRC regulations.

EFFECTIVE DATE: August 22, 1983.

FOR FURTHER INFORMATION CONTACT: Pearl Smith. Telephone: (312) 384–2728.

SUPPLEMENTARY INFORMATION: Effective August 22, 1983, the commercial telephone number for NRC's Region III office located at 799 Roosevelt Road, Glen Ellyn, Illinois will be changed to (312) 790–5500.

Because this is a nonsubstantive amendment dealing with a purely administrative matter of agency management, the notice and comment procedures of the Administrative Procedure Act (5 U.S.C. 553) do not apply and the amendment is effective August 22, 1983.

List of Subjects

10 CFR Part 20

Byproduct material, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Penalty, Radiation protection, Reporting and recordkeeping requirements, Special nuclear material, Source material, Waste treatment and disposal.

10 CFR Part 21

Nuclear power plants and reactors, Penalty, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 73

Hazardous materials—transportation, Incorporation by Reference, Nuclear material, Nuclear power plants and reactors, Penalty, Reporting and requirements, Security measures.

Under the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552, the following amendments to 10 CFR Parts 20, 21, and 73 are published as a document subject to codification.

The authority citation for this document is: (Sec. 161, Pub. L. 83–703, 68 Stat. 948, as amended (42 U.S.C. 2201)).

Because this is a non substantive amendment dealing with a purely administrative matter of agency management, the notice and comment procedures of the Administrative Procedure Act (5 U.S.C. 553) do not apply and the amendment is effective September 12, 1983.

List of Subjects

10 CFR Part 20

Byproduct material, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Penalty, Radiation protection, Reporting requirements, Special nuclear material, Source material, Waste treatment and disposal.

10 CFR Part 21

Nuclear power plants and reactors, Penalty, Radiation protection, Reporting requirements.

10 CFR Part 73

Hazardous materials-transportation, Incorporation by reference, Nuclear material, Nuclear power plants and reactors, Penalty, Reporting requirements, Security measures.

Under the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and the 5 U.S.C. 552, the following amendments to 10 CFR Parts 20, 21, and 73 are published as a document subject codification. The authority citation for this document is:

(Sec. 161, Pub. L. 83–703, 68 Stat. 948, as amended (42 U.S.C. 2201))

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48 FR 44172
Published 9/28/83
Effective 9/12/83

10 CFR Parts 20, 21, and 73

Commercial Telephone Number Change; Region III Office

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to indicate a change in the telephone number for the NRC's Region III Office. This document changes the implementation date of the previously announced change in the commercial telephone number and indicates a change in the FTS telephone number. The amendments are necessary to inform the public of these administrative changes to NRC regulations.

EFFECTIVE DATE: September 12, 1983.

FOR FURTHER INFORMATION CONTACT: Pearl Smidth, Telephone: (312) 384–2728.

SUPPLEMENTARY INFORMATION: In the Federal Register of August 25, 1983 (48 FR 38604), the Nuclear Regulatory Commission announced a change in the commercial telephone number for the NRC's Region III Office located at 799 Roosevelt Road, Glen Ellyn, Illinois, that was to have been effective in August 22, 1983. However, because of the recent telephone strike, this change did not occur as scheduled.

This document announces the new implementation date for the change in the commercial telephone number and also announces a changed FTS telephone number for the Region III Office. Effective 7:30 am CDT, September 12, 1983, the numbers for the Region III Office are changed to: Commercial—(312) 790–5500 and FTS—388–5500.

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49 FR 19623
Published 5/9/84
Effective 5/9/84

Information Collection Requirements; Display of OMB Control Numbers

See Part 0 Statements of Consideration

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49 FR 24513
Published 6/14/84
Effective 6/14/84

Change in Mailing Address for Submittal of Personnel Monitoring Reports

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations that affect NRC licensees who are required to submit periodic personnel monitoring reports. The amendments reflect the transfer of the occupational radiation exposure data collection function to a different NRC office, thus requiring a change in the mailing address.

EFFECTIVE DATE: June 14, 1984.

FOR FURTHER INFORMATION CONTACT: Barbara Brooks, Occupational Radiation Protection Branch, Division of Radiation Programs and Earth Sciences, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone 301–427–4577.

SUPPLEMENTARY INFORMATION: Effective January 8, 1984, the Office of Resource Management (RM) was reorganized in order to achieve more efficient use of its staff resources. Coincident with the reorganization, the former RM functions of collecting, reviewing, and coding radiation exposure information were transferred to the Occupational Radiation Protection Branch of the Office of Nuclear Regulatory Research.

This action is being taken in order to inform NRC licensees of the change in the mailing address to be used for the submittal of personnel monitoring reports. These amendments relate solely to minor matters of agency management and do not alter the rights or interests of licensees. Accordingly, the notice and comment procedures of the Administrative Procedure Act, 5 U.S.C. 553, are inapplicable and the amendments may be made effective on publication in the Federal Register.

Paperwork Reduction Act Statement

This final rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). Existing requirements were approved by the Office of Management and Budget approval number 3150–0014.

List of Subjects in 10 CFR Part 20

Byproduct material, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Penalty, Radiation protection, Reporting and recordkeeping requirements, Special nuclear material, Source material, Waste treatment and disposal.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is adopting the following amendments to 10 CFR Part 20.

Authority: The authority for this document is: Sec. 161, Pub. L. 83–703, 68 Stat. 948 (42 U.S.C. 2201), and Sec. 201, Pub. L. 93–438, 88 Stat. 1242, as amended (42 U.S.C. 5841).

> 49 FR 47823
Published 12/7/84
Effective 12/7/84

Minor Correcting Amendments

See Part 1 Statements of Consideration

PART 21

REPORTING OF DEFECTS AND NONCOMPLIANCE

GENERAL PROVISIONS

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21.61 Failure to notify.

Authority: Secs. 161i and 161o, Pub. L. 83-703, 68 Stat. 949 and 950, as amended, sec. 234, Pub. L. 91-161, 83 Stat. 444; secs. 201 and 206, Pub. L. 93-438, 88 Stat. 1242 and 1246, as amended (42 U.S.C. 2201(i), 2201(o), 2282, 5841, 5846).

GENERAL PROVISIONS

§ 21.1 Purpose.

The regulations in this part establish procedures and requirements for implementation of section 206 of the Energy Reorganization Act of 1974. That section requires any individual director or responsible officer of a firm constructing, owning, operating or supplying the components of any facility or activity which is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended, or the Energy Reorganization Act of 1974, who obtains information reasonably indicating: (a) That the facility, activity or basic component supplied to such facility or activity fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to substantial safety hazards or (b) that the facility, activity, or basic component supplied to such facility or activity contains defects, which could create a substantial safety hazard, to immediately notify the Commission of such failure to comply or such defect, unless he has actual knowledge that the Commission has been adequately informed of such defect or failure to comply. 42 FR 28891

§ 21.2 Scope.

The regulations in this part apply, except as specifically provided otherwise in Parts 31, 34, 35, 40, 60, 61, 70, or 72 of this chapter, to each individual, partnership, corporation, or other entity licensed pursuant to the regulations in this chapter to possess, use, and/or transfer within the United States source material, byproduct material, special nuclear material, and/or spent fuel, or to construct, manufacture, possess, own, operate and/or transfer within the United States, any production or utilization facility or independent spent fuel storage installation, and to each director (see § 21.3(f)) and responsible officer (see § 21.3(j)) of such a licensee. The regulations in this part apply also to each individual, corporation, partnership or other entity doing business within the United States, and each director and responsible officer of such organization, that constructs (see § 21.3(c)) a production or utilization facility licensed for manufacture, construction or operation (see § 21.3(h)) pursuant to Part 50 of this chapter or an independent spent fuel storage installation for the storage of spent fuel licensed pursuant to Part 72 of this chapter, or supplies (see § 21.3(l)) basic components (see § 21.3(a)) for a facility or activity licensed, other than for export, under Parts 30, 40, 50, 60, 61, 70, 71, or 72 of this chapter. Nothing in these regulations should be deemed to preclude either an individual or a manufacturer/supplier of a commercial grade item (see § 21.3(a-1)) not subject to the regulations in this part from reporting to the Commission a known or suspected defect or failure to comply and, as authorized by law, the identity of anyone so reporting will be withheld from disclosure.[1] 48 FR 38604

§ 21.3 Definitions.

As used in this part.

(a)(1) "Basic component," when applied to nuclear power reactors means a plant structure, system, component or part thereof necessary to assure (i) the integrity of the reactor coolant pressure boundary, (ii) the capability to shut down the reactor and maintain it in a safe shutdown condition, or (iii) the capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in § 100.11 of this chapter. 47 FR 57446

(2) "Basic component," when applied to other facilities and when applied to other activities licensed pursuant to Parts 30, 40, 50, 60, 61, 70, 71, or 72 of this chapter, means a component, structure, system, or part thereof that is directly procured by the licensee of a facility or activity subject to the regulations in this part and in which a defect (see § 21.3(d)) or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard (see § 21.3(k)).

(3) In all cases "basic component" includes design, inspection, testing, or consulting services important to safety that are associated with the component hardware, whether these services are performed by the component supplier or others.

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[1] NRC Regional Offices will accept collect telephone calls from individuals who wish to speak to NRC representatives concerning nuclear safety-related problems. The location and telephone numbers (for nights and holidays as well as regular hours) are listed below:

Region		
I	(Philadelphia)	(215) 337-5000
II	(Atlanta)	(404) 221-4503
III	(Chicago)	(312)790-5500
IV	(Dallas)	(817) 860-8100
IV	Uranium Recovery Field Office (Denver)	(303) 234-7232
V	(San Francisco)	(415) 943-3700

(4) A commercial grade item is not a part of a basic component until after dedication (see § 21.3(c–1)).

(a–1) "Commercial grade item" means an item that is (1) not subject to design or specification requirements that are unique to facilities or activities licensed pursuant to Parts 30, 40, 50, 60, 61, 70, 71, or 72 of this chapter and (2) used in applications other than facilities or activities licensed pursuant to Parts 30, 40, 50, 60, 61, 70, 71, or 72 of this chapter and (3) to be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example a catalog).

47 FR 57446

(b) "Commission" means the Nuclear Regulatory Commission or its duly authorized representatives.

(c) "Constructing" or "construction" means the design, manufacture, fabrication, placement, erection, installation, modification, inspection, or testing of a facility or activity which is subject to the regulations in this part and consulting services related to the facility or activity that are important to safety.

42 FR 28891

(c-1) "Dedication" of a commercial grade item occurs after receipt when that item is designated for use as a basic component.

43 FR 48621

(d) "Defect" means:

(1) A deviation (see § 21.3(e)) in a basic component delivered to a purchaser for use in a facility or an activity subject to the regulations in this part if, on the basis of an evaluation (see § 21.3(g)), the deviation could create a substantial safety hazard; or

42 FR 36803

(2) The installation, use, or operation of a basic component containing a defect as defined in paragraph (d)(1) of this section; or

(3) A deviation in a portion of a facility subject to the construction permit or manufacturing licensing requirements of Part 50 of this chapter provided the deviation could, on the basis of an evaluation, create a substantial safety hazard and the portion of the facility containing the deviation has been offered to the purchaser for acceptance; or

(4) A condition or circumstance involving a basic component that could contribute to the exceeding of a safety limit, as defined in the technical specifications of a license for operation issued pursuant to Part 50 of this chapter.

(e) "Deviation" means a departure from the technical requirements included in a procurement document (see § 21.3(i)).

(f) "Director" means an individual, appointed or elected according to law, who is authorized to manage and direct the affairs of a corporation, partnership or other entity. In the case of an individual proprietorship, "director" means the individual.

(g) "Evaluation" means the process accomplished by or for a licensee to determine whether a particular deviation could create a substantial safety hazard.

(h) "Operating" or "operation" means the operation of a facility or the conduct of a licensed activity which is subject to the regulations in this part and consulting services related to operations that are important to safety.

(i) "Procurement document" means a contract that defines the requirements which facilities or basic components must meet in order to be considered acceptable by the purchaser.

(j) "Responsible officer" means the president, vice-president or other individual in the organization of a corporation, partnership, or other entity who is vested with executive authority over activities subject to this part.

42 FR 28891

(k) "Substantial safety hazard" means a loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed, other than for export, pursuant to Parts 30, 40, 50, 60, 61, 70, 71, or 72 of this chapter.

47 FR 57446

(l) "Supplying" or "supplies" means contractually responsible for a basic component used or to be used in a facility or activity which is subject to the regulations in this part.

§ 21.4 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

§ 21.5 Communications.

Except where otherwise specified in this part, all communications and reports concerning the regulations in this part should be addressed to the Director, Office of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, or to the Director of a Regional Office at the address specified in Appendix D of Part 20 of this chapter. Communications and reports also may be delivered in person at the Commission's offices at 1717 H Street NW., Washington, D.C.; at 7920 Norfolk Avenue, Bethesda, Md.; or at a Regional Office at the location specified in Appendix D of Part 20 of this chapter.

§ 21.6 Posting requirements.

(a) Each individual, partnership, corporation or other entity subject to the regulations in this part, shall post current copies of the following documents in a conspicuous position on any premises, within the United States where the activities subject to this part are conducted (1) the regulations in this part, (2) Section 206 of the Energy Reorganization Act of 1974, and (3) procedures adopted pursuant to the regulations in this part.

(b) If posting of the regulations in this part or the procedures adopted pursuant to the regulations in this part is not practicable, the licensee or firm subject to the regulations in this part may, in addition to posting section 206, post a notice which describes the regulations/procedures, including the name of the individual to whom reports may be made, and states where they may be examined.

(c) The effective date of this section has been deferred until January 6, 1978.

42 FR 28891

42 FR 28891

§ 21.7 Exemptions.

The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

43 FR 48621

Suppliers of commercial grade items are exempt from the provisions of this part to the extent that they supply commercial grade items.

49 FR 19623

§ 21.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). OMB has approved the information collection requirements contained in this part under control number 3150-0035.

(b) The approved information collection requirements contained in this part appear in §§ 21.21 and 21.51.

NOTIFICATION

42 FR 28891

§ 21.21 Notification of failure to comply or existence of a defect.

(a) Each individual, corporation, partnership or other entity subject to the regulations in this part shall adopt appropriate procedures to:

(1) Provide for: (i) Evaluating deviations or (ii) informing the licensee or purchaser of the deviation in order that the licensee or purchaser may cause the deviation to be evaluated unless the deviation has been corrected; and

(2) Assure that a director or responsible officer is informed if the construction or operation of a facility, or activity, or a basic component supplied for such facility or activity:

(i) Fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order or license of the Commission relating to a substantial safety hazard, or

(ii) Contains a defect. The effective date of this paragraph has been deferred until January 6, 1978.

47 FR 57446

(b)(1) A director or responsible officer subject to the regulations of this part or a designated person shall notify the Commission when he obtains information reasonably indicating a failure to comply or a defect affecting (i) the construction or operation of a facility or an activity within the United States that is subject to the licensing requirements under Parts 30, 40, 50, 60, 61, 70, 71, or 72 of this chapter and that is within his organization's responsibility or (ii) a basic component that is within his organization's responsibility and is supplied for a facility or an activity within the United States that is subject to the licensing requirements under Parts 30, 40, 50, 60, 61, 70, 71, or 72 of this chapter. The above notification is not required if such individual has actual knowledge that the Commission has been adequately informed of such defect or such failure to comply.

42 FR 28891

(2) Initial notification required by this paragraph shall be made within two days following receipt of the information. Notification shall be made to the Director, Office of Inspection and Enforcement, or to the Director of a Regional Office. If initial notification is by means other than written communication, a written report shall be submitted to the appropriate Office within 5 days after the information is obtained. Three copies of each report shall be submitted to the Director, Office of Inspection and Enforcement.

(3) The written report required by this paragraph shall include, but need not be limited to, the following information, to the extent known:

(i) Name and address of the individual or individuals informing the Commission.

(ii) Identification of the facility, the activity, or the basic component supplied for such facility or such activity within the United States which fails to comply or contains a defect.

(iii) Identification of the firm constructing the facility or supplying the basic component which fails to comply or contains a defect.

(iv) Nature of the defect or failure to comply and the safety hazard which is created or could be created by such defect or failure to comply.

(v) The date on which the information of such defect or failure to comply was obtained.

(vi) In the case of a basic component which contains a defect or fails to comply, the number and location of all such components in use at, supplied for, or being supplied for one or more facilities or activities subject to the regulations in this part.

(vii) The corrective action which has been, is being, or will be taken; the name of the individual or organization responsible for the action; and the length of time that has been or will be taken to complete the action.

(viii) Any advice related to the defect or failure to comply about the facility, activity, or basic component that has been, is being, or will be given to purchasers or licensees.

(4) The director or responsible officer may authorize an individual to provide the notification required by this paragraph, provided that, this shall not relieve the director or responsible officer of his or her responsibility under this paragraph.

(c) Individuals subject to paragraph (b) of this section may be required by the Commission to supply additional information related to the defect or failure to comply.

PROCUREMENT DOCUMENTS

§ 21.31 Procurement documents.

Each individual, corporation, partnership or other entity subject to the regulations in this part shall assure that each procurement document for a facility, or a basic component issued by him, her or it on or after January 6, 1978 specifies, when applicable, that the provisions of 10 CFR Part 21 apply.

INSPECTIONS, RECORDS

§ 21.41 Inspections.

Each individual, corporation, partnership or other entity subject to the regulations in this part shall permit duly authorized representatives of the Commission, to inspect its records, premises, activities, and basic components as necessary to effectuate the purposes of this part.

42 FR 2889

§ 21.51 Maintenance of records.

(a) Each licensee of a facility or activity subject to the regulations in this part shall maintain such records in connection with the licensed facility or activity as may be required to assure compliance with the regulations in this part.

(b) Each individual, corporation, partnership, or other entity subject to the regulations in this part shall prepare records in connection with the designs, manufacture, fabrication, placement, erection, installation, modification, inspection, or testing of any facility, basic component supplied for any licensed facility or to be used in any licensed activity sufficient to assure compliance with the regulations in this part. After delivery of the facility or component and prior to the destruction of the records relating to evaluations (see § 21.3(g)) or notifications to the Commission (see § 21.21), such records shall be offered to the purchaser of the facility or component. If such purchaser determines any such records:

(1) Are not related to the creation of a substantial safety hazard, he may authorize such records to be destroyed, or

(2) Are related to the creation of a substantial safety hazard, he shall cause such records to be offered to the organization to which he supplies basic components or for which he constructs a facility or activity.

If such purchaser is unable to make the determination as required above then the responsibility for making the determination shall be transferred to the individual, corporation, partnership, or other entity subject to the regulations in this part that issued the procurement document to the purchaser. In the event that the determination cannot be made at that level then the responsibility shall be transferred in a similar manner to another individual, corporation, partnership, or other entity subject to the regulations in this part, until, if necessary, the licensee shall make the determination.

(c) Records that are prepared only for the purpose of assuring compliance with the regulations in this part and are not related to evaluations or notifications to the Commission may be destroyed after delivery of the facility or component.

(d) The effective date of the section has been deferred until January 6, 1978.

42 FR 28891

ENFORCEMENT

§ 21.61 Failure to notify.

Any director or responsible officer subject to the regulations in this part who knowingly and consciously fails to provide the notice required by § 21.21 shall be subject to a civil penalty equal to the amount provided by section 234 of the Atomic Energy Act of 1954, as amended.

46 FR 13202

[Note removed 49 FR 19623]

PART 21

REPORTING OF DEFECTS AND NONCOMPLIANCE

PROPOSED RULE MAKING

50 FR 13797
Published 4/8/85
Comment period expires 7/8/85

Licenses and Radiation Safety Requirements for Well-Logging Operations

See Part 39 Proposed Rule Making

UNITED STATES NUCLEAR REGULATORY COMMISSION
RULES and REGULATIONS
TITLE 10, CHAPTER 1, CODE OF FEDERAL REGULATIONS—ENERGY

PART 21
REPORTING OF DEFECTS AND NONCOMPLIANCE

STATEMENTS OF CONSIDERATION

42 FR 28891
Published 6/6/77
Effective 7/6/77; §§21.6, 21.21(a) and 21.51 effective 1/6/78
(7/6/77 effective date extended to 8/10/77)

Reports to the Commission Concerning Defects and Noncompliance

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations to require directors and responsible officers of firms and organizations building, operating or owning NRC-licensed facilities, or conducting NRC-licensed activities, to report failures to comply with regulatory requirements and defects in components which may result in a substantial safety hazard. Also covered under the new regulations are directors and responsible officers of firms and organizations supplying safety-related components, including safety-related design, testing, inspection and consulting services.

NRC licensees and other firms and organizations covered by the new regulations must adopt internal procedures to assure that safety-related defects and noncompliance are brought to the attention of responsible officers and directors. Those individuals, in turn, will be required to notify the Commission within two days, and file a written report within five days, of learning of the defect or noncompliance. Directors and responsible officers may designate an employee to provide on their behalf the notification to NRC.

EFFECTIVE DATE: July 6, 1977. Certain obligations under the effective rule are not imposed until January 6, 1978.

FOR FURTHER INFORMATION CONTACT:

Mr. W. E. Campbell, Jr., Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Phone 301-443-6917.

SUPPLEMENTARY INFORMATION: On March 3, 1975, the Nuclear Regulatory Commission published in the FEDERAL REGISTER (40 FR 8832) for public comment proposed amendments to 10 CFR Parts 2, 31, 35, and 40 of its regulations and a proposed new Part 21 to its regulations, "Reporting of Defects and Noncompliance."

The purpose of these proposed amendments and the new proposed Part 21 is to implement section 206 of Pub. L. 93-438, the Energy Reorganization Act of 1974, as amended.

Section 206 of the Energy Reorganization Act of 1974 as amended, reads as follows:

"NONCOMPLIANCE

Sec. 206. (a) Any individual director, or responsible officer of a firm constructing, owning, operating, or supplying the components of any facility or activity which is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended, or pursuant to this Act, who obtains information reasonably indicating that such facility or activity or basic components supplied to such facility or activity—

(1) Fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to substantial safety hazards, or

(2) Contains a defect which could create a substantial safety hazard, as defined by regulations which the Commission shall promulgate, shall immediately notify the Commission of such failure to comply, or of such defect, unless such person has actual knowledge that the Commission has been adequately informed of such defect or failure to comply.

(b) Any person who knowingly and consciously fails to provide the notice required by subsection (a) of this section shall be subject to a civil penalty in an amount equal to the amount provided by section 234 of the Atomic Energy Act of 1954, as amended.

(c) The requirements of this section shall be prominently posted on the premises of any facility licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended.

(d) The Commission is authorized to conduct such reasonable inspections and other enforcement activities as needed to insure compliance with the provisions of this section."

The new Part 21 requires that the directors and responsible officers of organizations that construct, own, operate or supply components of a facility or activity that is licensed or otherwise regulated by the Nuclear Regulatory Commission inform the Commission if they obtain information reasonably indicating that such facility, activity or basic component fails to comply with regulatory requirements relating to substantial safety hazards or that such facility, activity, or basic component contains a defect which could create a substantial safety hazard. Part 21 additionally requires that these organizations establish procedures to evaluate deviations from the technical requirements of the procurement documents or inform the purchaser concerning the deviation in order that the purchaser evaluate the deviation or have it evaluated. The organizations subject to the regulations in Part 21 may be many procurement tiers away from the holder of a license to construct or operate a nuclear power reactor. If the license is other than to construct or operate a nuclear power reactor, then the organizations subject to the regulations are those organizations that directly supply the licensee of the facility or activity. The directors and responsible officers of these organizations will be subject to a fine of up to $5,000 for each deliberate failure to notify the Commission of the existence of such a defect or noncompliance. The organizations subject to Part 21 regulations must also maintain records, post copies of specific documents, inform procurement subtier suppliers of their responsibility under Part 21 and allow inspection of their premises, facilities and activities by duly authorized representatives of the Commission.

The Commission requires that a number of reports and notifications be submitted by licensees. These include licensee's report of incidents required by 10 CFR § 20.403, permit holder's notification of design or construction deficiencies required by 10 CFR § 50.55(e)(1), and licensee's report of theft or attempted theft of special nuclear material required by 10 CFR § 70.52. Other Commission regulations provide for receipt of various kinds of requests or information. For example, 10 CFR § 2.802 provides for petitions to issue, amend or rescind regulations, and 10 CFR § 19.16 provides for notifications from workers in regard to radiological hazards. These communications from licensees and the public are methods of securing information concerning the implementation effectiveness of Commission regulations. This information is an essential ingredient of sound regulation. The regulations in Part 21 add another required notification. Moreover, a longstanding Commission policy encourages individuals not subject to the Commission's regulations to report to the Commission a known or suspected defect or failure to comply; as authorized by law, the identity of anyone so reporting will be withheld from disclosure.

The Commission intends to examine closely the implementation of new Part 21 with a view to making any clarifying or other changes that may be warranted in light of experience. In particular, insufficient experience has been accumulated to permit the writing of a detailed regulation at this time that would provide a precise correlation of all factors pertinent to the question of what is a significant safety hazard. Part 21 is intended in this regard as an initial effort to identify a number of the factors involved with the question of significant safety hazard. Further, additional guidance in the form of regulatory guides may be developed should experience with the application of Part 21 indicate the need for such guidance. In this regard, we expect that the implementation efforts of the staff and those subject to the rule, and the views of interested members of the public, should provide the necessary data base for such further guidance.

During the development of the Energy Reorganization Act, Congress identified a need for an effective means to "anticipate problems before the event." Section 206 was developed to fill that need.

Interested persons have been afforded an opportunity to participate in the development of Part 21 and the associated amendments. The more important changes made to Part 21 are listed below and are based largely on consideration of public comments.

(1) The individuals subject to the notification requirement of Part 21 have been restricted to (a) directors and (b) officers vested with executive authority over activities subject to this part. These individuals may identify an individual that is authorized to provide notification to the Commission.

This new part is only one of many of the reporting channels that concerns defects or noncompliance, e.g., 10 CFR 50.55(e). Individuals that are subject to the requirements of this part that become aware of a defect or noncompliance that is outside the responsibility of their organization and individuals that are not subject to the requirements of any part of Title 10 are encouraged, but not required, to report to the Commission known or suspected defects or failure to comply. As authorized by law, the identity of anyone so reporting will be withheld from disclosures.

(2) Part 21, as adopted, does not specify whether firms may reimburse directors or responsible officers for civil penalties imposed pursuant to these regulations, and instead allows this question to be resolved in accordance with applicable state law.[1]

(3) The definition of "defect," as applied to components themselves, has been restricted to include those deviations in delivered components from technical requirements included in the procurement document that could, on the basis of an evaluation, create a substantial safety hazard. Defect also includes a deviation in a portion of the facility subject to the construction permit or manufacturing licensing requirement of Part 50 provided the deviation could, on the basis of an evaluation, create a substantial safety hazard and the portion of the facility containing the deviation has been offered to the purchaser for acceptance. Whether such deviation could result in a substantial safety hazard is determined during the deviation evaluation. Defect also includes, for facilities licensed for operation under Part 50, any condition or circumstance involving a basic component that could contribute to the exceeding of a safety limit as set forth in the operating license technical specifications.

(4) The definition of basic components has been divided into two parts: one part is applicable to power reactors licensed under Part 50 and the second part is applicable to activities licensed pursuant to Parts 30, 40, 70 or 71 and to other Part 50 facilities. For power reactors the definition is based on the guidance given in Regulatory Guide 1.29. For other facilities and activities, basic component has been defined as components that are directly procured by a licensee.

(5) Substantial safety hazard has been defined in terms of a major reduction in the degree of protection provided to the public health and safety. Criteria that are appropriate for determination of creation of a substantial safety hazard include:

Moderate exposure to, or release of, licensed material.

Major degradation of essential safety-related equipment.

Major deficiencies involving design, construction, inspection, test or use of licensed facilities or material.

To the extent that failures to comply or defects in a security system can contribute to a substantial safety hazard, such failures and defects are within the scope of Part 21.

(6) Clarification has been added in regard to which organizations are subject to the regulations in this part. In order that the implementation of Section 206 may be responsive to anticipation of problems before the event, a broad interpretation of "firm constructing, owning, operating or supplying the components" has been used. This interpretation includes not only licensees and organizations that physically construct facilities and physically supply components but also includes organizations that only supply safety-related services such as design, inspection, testing or consultation; e.g., site geological investigations.

This interpretation is intended to bring within the regulations in this part those various organizations that can create a substantial safety hazard considering the various methods available for consultation, procurement, design, construction, testing, inspection and operation. These methods include not only the option where design and construction are accomplished by one organization but also the option where one organization does safety-related consultation, another safety-related design and another the actual construction. Each of these organizations has the capability to generate a defect and a potential for failing to comply.

If a basic component is fabricated by one organization using a design from another organization, the possibility of creating a substantial safety hazard, based upon a faulty design, exists upon the delivery of the design that fails to comply or contains a defect. A substantial safety hazard, based upon faulty fabrication, exists upon delivery of the item that fails to comply or contains a defect. In many instances the competent fabricating organization possesses neither the capability nor the responsibility for design.

It is realized that during the activities of design and consultation there may be a stage of conceptual design or consultation in regard to feasibility. Only when such a design or consultation can result in the creation of a substantial safety hazard is it appropriate to specify the applicability of Part 21 in the procurement document.

(7) The organizations subject to this part must establish procedures to provide for correction of deviations, or evaluation of deviations or informing purchasers of the deviation so the purchaser may evaluate the deviation. These procedures must also provide for informing a responsible officer or director of the organization of any resulting defect or failure to comply.

(8) The provisions of Part 21 imposing requirements that procurement documents state, when applicable, that Part 21 applies would be applicable only to future procurements of facilities, components or services; i.e., procured on or after six months after the effective date of Part 21.

The effective date of § 21.6 dealing with posting requirements, § 21.21(a) dealing with adopting procedures, and § 21.51 dealing with maintenance of records has been deferred until January 6, 1978, to allow organizations to establish and implement procedures.

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[1] While agreeing with all other aspects of this Notice, Commissioner Gilinsky believes firms should be barred from reimbursing directors or responsible officers for civil penalties imposed pursuant to Part 21, on grounds that Section 206 of the Energy Reorganization Act is designed to impose personal responsibility, a goal undermined by corporate indemnification. The Commission majority believes that, in accordance with the general practice of federal regulatory bodies in analogous matters, the question of the reimbursability of such penalties should be governed by applicable state law. It notes that the adverse publicity attendant on being subjected to a civil penalty for knowingly concealing significant safety information would be a major incentive to compliance, irrespective of whether the person so penalized was later reimbursed by the company. The majority also recognizes the serious practical difficulty in attempting to differentiate between a properly awarded salary increase or bonus and an improper reimbursement. If Part 21 does not in practice appear to be accomplishing its purpose, the Commission will, of course, propose changes deemed appropriate in light of experience.

(9) The organizations subject to the regulations in Part 21 are required to prepare records in connection with their activities to assure compliance with this part. Prior to destruction of such records they shall be offered to the purchaser. It is not anticipated that these documentation requirements will necessitate any change in the documentation procedures of organizations that are presently complying with 10 CFR 50 Appendix B, "Quality Assurance Criteria."

(10) Clarification has been added in regard to the applicability of Part 21 to the licensed activity of exporting. Persons who are only licensed to export nuclear facilities or materials and who do not otherwise construct or operate facilities or activities or supply components are not subject to the new part. Individuals subject to this part need report only defects or failures to comply which could create a substantial safety hazard in facilities and activities within the United States. Further, any notification submitted in accordance with Part 21 may be exempt from public disclosure as authorized by law.

After consideration of the comments received and other factors, the Commission has adopted the amendments to Parts 2, 31, 34, 35, 40, and 70, and the new Part 21 set forth below.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of title 5 of the United States Code, the following new Part 21 of Title 10, Chapter 1 of the Code of Federal Regulations, and amendments to Parts 2, 31, 34, 35, 40, and 70 are published as a document subject to codification to be effective on July 6, 1977.

42 FR 36803
Published 7/18/77
Effective 8/10/77

REPORTS TO THE COMMISSION CONCERNING DEFECTS AND NONCOMPLIANCE

Correction

In FR Doc. 77-15987 appearing on page 28891 in the issue for Monday, June 6, 1977, on page 28894, § 21.3 (a)(3) should read as follows:

43 FR 48621
Published 10/19/78
Effective 10/19/78
Comment period expires 12/18/78

PART 21—REPORTING OF DEFECTS AND NONCOMPLIANCE

Amendments Regarding Basic Component

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations to limit the types of items that are within the scope of its rule for reporting defects and noncompliance. This action is believed necessary since the currently effective rule is being applied by organizations within its scope to an extent not contemplated and is causing problems relating to the supplying of equipment. The amendments provide that items that are available in general commerce and which have no unique requirements imposed for nuclear application will not be within the scope of the revised rule for reporting defects and noncompliance. These amendments will alleviate the above problem.

DATE: These amendments will be effective on October 19, 1978.

FOR FURTHER INFORMATION CONTACT:

Mr. W. E. Campbell, Jr., Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, 301-443-5913.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Nuclear Regulatory Commission (hereinafter the "Commission") has decided to amend 10 CFR Part 21, "Reporting of Defects and Noncompliance." Specifically, the Commission has decided to impose limits on the types of items that are used in facilities or activities licensed pursuant to part 30, 40, 50, 70, or 71 that are within the scope of 10 CFR Part 21.

On March 3, 1975, 10 CFR Part 21 was published as a proposed rule (40 FR 8832). On June 6, 1977, 10 CFR Part 21 was published as an effective rule (42 FR 28891) with some portions of the rule to be effective on July 6, 1977, and the remaining portions to be effective on January 6, 1978. On July 7, 1977, a FEDERAL REGISTER notice (42 FR 34886) changed the initial effective date to August 10, 1977, vice July 6, 1977. To facilitate implementation of 10 CFR Part 21 a series of public regional meetings were held in July 1977 and based on those meetings the Commission staff in October 1977 published NUREG-0302 Rev. 1, "Remarks Presented (Questions/Answers) Discussed at the Public Regional Meetings To Discuss Regulations (10 CFR Part 21) for Reporting Defects and Noncompliance." NUREG-0302 Rev. 1 contains staff guidance relating to the implementation and enforcement of 10 CFR Part 21 and is available through the National Technical Information Service, Springfield, Va. 22161. In the preamble to the effective rule, the Commission stated that it intended "to examine closely the implementation of 10 CFR Part 21 with a view to making any clarifying or other changes that may be warranted in the light of experience."

Part 21 defines a "basic component" subject to the reporting and other requirements of the rule. In response to inquiries during and subsequent to the public regional meetings relating to "off-the-shelf" or "catalog" items, the staff provided guidance that such items may be within the scope of 10 CFR Part 21 depending on the circumstances at the time of procurement. This guidance has been construed by numerous organizations to mean that the requirements of 10 CFR Part 21 apply to manufacturers and distributors who are involved to any extent in supplying basic components, or parts of basic components, of a facility or activity including supplying base material or functional assemblies to the manufacturer of the "basic component." This meaning has led to the imposition of 10 CFR Part 21 at a procurement stage where there are no design or specification requirements that are unique to application of the item at a nuclear facility or activity, e.g., relays.

The use of this meaning of basic component has not improved the quality of such items and, therefore, has not enhanced safety. Instead it is causing cost increases and inability to obtain needed supplies. To the extent that the purchaser is unable to obtain a needed item from the most qualified supplier and must turn to other less qualified suppliers, defining basic component to include such an item may to some extent detract from safety. To relieve the conditions that are resulting from the above interpretation and to mitigate this potential reduction of safety part 21 is being amended to remove from the scope of 10 CFR Part 21, during specific stages of procurement, those items of a commercial grade, e.g., bearings, relays, and bar stock that are (1) not subject to design or specification requirements unique to facilities or activities licensed by the Commission, (2) used in applications other than facilities or activities licensed by the Commission, and (3) able to be ordered from the manufacturer/distributor on the basis of the manufacturer's published specifications. At a defined stage of procurement, when the item is "dedicated" to a "basic component" (see 10 CFR 21.3(c-1)) the item will become subject to the requirements of 10 CFR Part 21.

Prior to these amendments 10 CFR Part 21 included within its scope direct inspections of licensees and suppliers as provided under section 206 of the Energy Reorganization Act of 1974. The revised rule will narrow the scope of the NRC inspection authority based on 10 CFR Part 21. However, NRC will retain the authority to inspect suppliers of commercial grade items provided by subsection 206(d) where reasonably necessary to aid in the identification by the Commission of defects and noncompliance reportable by licensees and suppliers of basic components as provided in 10 CFR Part 21.

Procurement documents that were issued in accordance with 10 CFR 21.31 after August 10, 1977, and invoked 10 CFR Part 21 may be amended to delete reference to 10 CFR Part 21 if the item being procured complies with the definition of a "commercial grade item" (see 10 CFR 21.3(a-1)).

The amended rule will clarify the applicability of 10 CFR Part 21 and thereby allow for precise application of the rule to those items that are subject to design or specification requirements unique to facilities or activities licensed pursuant to part 30, 40, 50, 60, or 71 of 10 CFR Chapter I.

Since the amendments are intended, in part, to respond to a number of requests for exemptions from 10 CFR Part 21 which may be necessary to insure the continued availability of components for the nuclear industry and since the amendments narrow the scope of the regulation thereby relieving a restriction on persons subject to it, but without any significant adverse safety consequences, the Commission has found that good cause exists for omitting notice of proposed rulemaking and public procedure thereon as unnecessary. Accordingly, the amendments are to be effective October 19, 1978.

Public comments on these amendments and on other portions of 10 CFR Part 21 are invited in order to evaluate the need for any further clarifying or other changes to 10 CFR Part 21. Comments that are received prior to December 18, 1978, will be particularly useful in evaluating the need for and content of additional amendments.

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46 FR 13202
Published 2/20/81
Effective 2/20/81

10 CFR Part 21

Statutory Increase in Civil Penalty Limits for Violations of Part 21

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations governing the reporting of defects and noncompliance, 10 CFR Part 21, to reflect the statutory increase in the monetary amount of civil penalties which the Commission may impose pursuant to Section 234 of the Atomic Energy Act of 1954, as amended. This amendment affects individual directors or responsible officers of firms constructing, owning, operating or supplying the components of any facility or activity which is licensed or regulated under the Atomic Energy Act of 1954, as amended, or the Energy Reorganization Act of 1974, as amended.

EFFECTIVE DATE: February 20, 1981.

FOR FURTHER INFORMATION CONTACT: Bruce A. Berson, Office of the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Telephone (301) 492-7678.

SUPPLEMENTARY INFORMATION: Section 206 of the Energy Reorganization Act of 1974, as amended, 42 U.S.C. 5846, requires individual directors or responsible officers of firms constructing, owning, operating, or supplying the components of any facility or activity which is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended (Atomic Energy Act), or the Energy Reorganization Act who obtain information reasonably indicating that such facility or activity or basic components supplied to such facility or activity (1) fails to comply with the Atomic Energy Act or any applicable rule, regulation, order, or license of the Nuclear Regulatory Commission (Commission) relating to substantial safety hazards, or (2) contains a defect which could create a substantial safety hazard, as defined by regulations which the Commission shall promulgate, to immediately notify the Commission of such failure to comply, or of such defect, unless such person has actual knowledge that the Commission has been adequately informed of such defect or failure to comply. Subsection 206(b) of the Energy Reorganization Act specifically provides that any person who knowingly and consciously fails to provide the required notice is subject to a civil penalty in an amount equal to the amount provided by Section 234 of the Atomic Energy Act, 42 U.S.C. 2282.

Section 234 of the Atomic Energy Act, "Civil Monetary Penalties for Violation of Licensing Requirements," was recently amended by Congress. The maximum civil penalty per violation was increased from $5,000 to $100,000 and the "cap" which limited the total penalty for violations occurring during a 30-day period to $25,000 was eliminated.[1] Therefore, persons who knowingly and consciously fail to provide the notice required by section 206 of the Energy Reorganization Act are now subject to civil penalties of up to $100,000 per violation.[2]

The Commission's regulations implementing the requirements of Section 206 of the Energy Reorganization Act are codified in 10 CFR Part 21, "Reporting of Defects and Noncompliance." Section 21.61 of the regulation specifies the monetery limits on civil penalties which the Commission may assess for failures to comply with the notification requirements of Part 21. However, § 21.61 does not presently reflect the statutory increase in the amount of civil penalties which the Commission may assess pursuant to amended section 234 of the Atomic Energy Act. Therefore, § 21.61 is amended to account for the increase. The amended regulation references the civil penalty limits of section 234 of the Atomic Energy Act without repeating in the regulation the precise dollar figures set forth in the statute. This avoids the necessity of amending 10 CFR 21.61 again should the Congress subsequently amend the dollar limits in section 234 of the Atomic Energy Act.

Since the amendment to 10 CFR 21.61 is required to comply with the statutory increase in the monetary amount of civil penalties which the Commission may impose pursuant to section 234 of the Atomic Energy Act, the Commission has found that good cause exists for omitting notice of proposed rulemaking and public procedure thereon as unnecessary and for making the amendment effective upon publication in the **Federal Register** without the customary 30-day notice.

Accordingly, pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendment to Title 10, Chapter I, Code of Federal Regulations, Part 21 is published as a document subject to codification, to be effective on February 20, 1981.

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[1] Section 206, Nuclear Regulatory Commission FY 1980 Appropriation Authorization, Pub. L. 96-295, 94 Stat. 787, June 30, 1980.

[2] In this regard the Conference Report H.R. Rep. No. 96-1070 at 34, states that "the conferees intend that the increased limits contained in the provision of the conference agreement [amended section 234 of the Atomic Energy Act] will also apply to civil penalties imposed pursuant to section 206 of the Energy Reorganization Act of 1974."

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46 FR 58281
Published 12/1/81
Effective 12/1/81

Licensing Requirements for the Storage of Spent Fuel in an Independent Spent Fuel Storage Installation; Minor Clarifying and Conforming Amendments

See Part 72 Statements of Consideration

47 FR 41336
Published 9/20/82
Effective 9/20/82

Minor Clarifying Amendments

See Part 1 Statements of Consideration

47 FR 57446
Published 12/27/82
Effective dates:
10 CFR 20.311 of Part 20 effective date is 12/27/83; 10 CFR Part 61 and all other changes effective 1/26/83.

Licensing Requirements for Land Disposal of Radioactive Waste

See Part 61 Statements of Consideration

48 FR 38604
Published 8/26/83
Effective 8/22/83

Minor Clarifying Amendments

See Part 20 Statements of Consideration

48 FR 44172
Published 9/28/83
Effective 9/12/83

Commercial Telephone Number Change; Region III Office

See Part 20 Statements of Consideration

> **49 FR 19623**
Published 5/9/84
Effective 5/9/84

Information Collection Requirements; Display of OMB Control Numbers

See Part 0 Statements of Consideration

PART 25

ACCESS AUTHORIZATION FOR LICENSEE PERSONNEL

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48 FR 35069

Authority: Secs. 145, 161, 68 Stat. 942, 948, as amended (42 U.S.C. 2165, 2201); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); E.O 10865, as amended, 3 CFR 1959–1963 COMP., p. 398 (50 U.S.C. 401, note); E.O. 12356, 47 FR 14874, April 6, 1982.

Appendix A also issued under 96 Stat. 1051 (31 U.S.C. 9701).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273), §§ 25.13, 25.17(a), 25.33 (b) and (c) are issued under sec. 161i, 68 Stat. 949, as amended (42 U.S.C. 2201(i)), and §§ 25.13 and 25.33(b) are also issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

48 FR 24318

General Provisions

§ 25.1 Purpose.

This part establishes procedures for granting, reinstating, extending, transferring and terminating access authorizations of licensee personnel, licensee contractors or agents and other persons (e.g. individuals involved in adjudicatory procedures as set forth in 10 CFR Part 2, Subpart I) who may require access to information classified at the Secret and Confidential National Security Information and/or Restricted Data level.

45 FR 14476

§ 25.3 Scope.

The regulations in this part apply to licensees and others who may require access to National Security Information and/or Restricted Data related to a license or application for a license.

§ 25.5 Definitions.

47 FR 38675

"Access authorization" means an administrative determination that an individual (including a consultant) who is employed by or an applicant for employment with the NRC, NRC contractors, agents, and licensees of the NRC, or other person designated by the Executive Director for Operations, is eligible for a security clearance for access to Restricted Data or national security information.

46 FR 58281

"Act" means the Atomic Energy Act of 1954 (68 Stat. 919), as amended.

"Commission" means the Nuclear Regulatory Commission or its duly authorized representatives.

"L" access authorization means an access authorization granted by the Commission which is normally based on a National Agency Check (NAC) or NAC and Inquiry (NACI) conducted by the Office of Personnel Management.

"License" means a license issued pursuant to 10 CFR Parts 50, 70, or 72.

"Matter" means documents or material.

48 FR 24318

"National Security Information" means information that has been determined pursuant to Executive Order 12356 or any predecessor order to require protection against unauthorized disclosure and that is so designated.

45 FR 14476

"Need-to-know" means a determination by persons having responsibility for classified information or matter, that a proposed recipient's access to such classified information or matter is necessary in the performance of his official, contractual, or licensee duties of employment under the cognizance of the Commission.

"Person" means (1) any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, government agency other than the Commission or the Department of Energy (DOE), except that the DOE shall be considered a person to the extent that its facilities are subject to the licensing and related regulatory authority of the Commission pursuant to section 202 of the Energy Reorganization Act of 1974 and sections 104, 105 and 202 of the Uranium Mill Tailings Radiation Control Act of 1978, any State or any political subdivision of, or any political entity within a State, any foreign government or nation or any political subdivision of any such government or nation, or other entity; and (2) any legal successor, representative, agent, or agency of the foregoing.

"Q" Access Authorization means an access authorization granted by the Commission based on a full field investigation conducted by the Office of Personnel Management, the Federal Bureau of Investigation, or other U.S. Government agency which conducts personnel security investigations.

"Restricted Data" means all data concerning design, manufacture or utilization of atomic weapons, the production of special nuclear material, or the use of special nuclear material in the production of energy, but shall not include data declassified or removed from the Restricted Data category pursuant to Section 142 of the Act.

§ 25.7 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

§ 25.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). OMB has approved the information collection requirements contained in this part under control number 3150-0046.

(b) The approved information collection requirements contained in this part appear in §§ 25.11, 25.17, 25.21, 25.23, 25.25, 25.27, 25.29, 25.31, 25.33, and 25.35.

49 FR 19623

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In § 25.17, Form NRC-1 is approved under control number 3150-0048.

(2) In § 25.17, Form NRC-237 is approved under control number 3150-0050.

(3) In § 25.33, Form NRC-136 is approved under control number 3150-0049.

(4) In § 25.35, Form NRC-277 is approved under control number 3150-0051.

PART 25 • ACCESS AUTHORIZATION FOR LICENSEE PERSONNEL

§ 25.9 Communications.

Except where otherwise specified, all communications and reports concerning the regulations in this part should be addressed to the Director, Division of Security, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

§ 25.11 Specific exemptions.

45 FR 14476

The Commission may, upon application of any interested party, grant an exemption from the requirements of this Part 25. Exemptions will be granted only if they are authorized by law and will not constitute an undue risk to the common defense and security. Documentation related to the request, notification and processing of an exemption shall be maintained for two years beyond the period covered by the exemption.

§ 25.13 Records maintenance.

Each licensee or organization employing individuals approved for personnel security access authorization under this part, shall maintain records as prescribed within the part. These records shall be subject to review and inspection by NRC representatives during security surveys.

Access Authorizations

§ 25.15 Access permitted under "Q" or "L" access authorization.

(a) A "Q" access authorization permits an individual access on a need-to-know basis to (1) Secret and Confidential Restricted Data and (2) Secret and Confidential National Security Information including intelligence information, CRYPTO (i.e., cryptographic information) or other classified communications security (COMSEC) information.

(b) An "L" access authorization permits an individual access on a need-to-know basis to Confidential Restricted Data and Secret and Confidential National Security Information other than the categories specifically included in paragraph (a) of this section.

47 FR 9194

(c) Each employee of the Commission is processed for one of the two levels of access authorization. Licensees and other persons will furnish National Security Information and/or Restricted Data to a Commission employee on official business when the employee has the appropriate level of NRC access authorization and need-to-know. Some individuals are permitted to begin NRC employment without an access authorization. However, no NRC employee shall be permitted access to any classified information until the appropriate level of access authorization has been granted to that employee by NRC.

§ 25.17 Approval for processing applicants for access authorization.

48 FR 24318

(a) Access authorizations shall be requested for licensee employees or other persons (e.g., 10 CFR Part 2, Subpart I) who need access to National Security Information and/or Restricted Data in connection with activities under Parts 50, 70, or 72.

47 FR 9194

(b) The request must include a completed personnel security packet (see § 25.17(c)) and request form (NRC-237) signed by a licensee or licensee contractor official.

48 FR 24318

(c)(1) Each personnel security packet submitted, must include the following completed forms:

(i) Personnel Security Questionnaire (NRC-1, Parts I and II);

(ii) National Agency Check-Data for Nonsensitive or Noncritical-Sensitive Position (SF-85-A)—for "L" cases only;

(iii) Two Standard Fingerprint cards (FD-258);

(iv) Security Acknowledgment (NRC-176);

(v) Authority to Release Information (NRC-259); and

(vi) Related forms where specified in accompanying instructions (NRC-254).

(2) Forms identified in paragraphs (c)(1) (i) and (ii) of this section must be typed. Only a Security Acknowledgment (NRC Form 176) need be completed by any person possessing an active access authorization, or who is being processed for an access authorization, by another Federal agency. The active or pending access authorization must be at an equivalent level to that required by the NRC and be based on an adequate investigation not more than five years old.

45 FR 14476

(d) To avoid delays in processing requests for access authorizations, each security packet should be reviewed for completeness and correctness (including legibility of response on the forms) prior to submittal.

48 FR 27533

(e) Applications for access authorization processing must be accompanied by a check or money order, payable to the United States Nuclear Regulatory Commission, representing the current cost for the processing of each "Q" and "L" access authorization request. Access authorization fees will be published in July of each year and will be applicable to each access authorization request received upon or after the date of publication. Applications from individuals having current Federal access authorizations may be processed expeditiously at less cost, since the Commission may accept the certification of access authorization and investigative data from other Federal Government agencies which grant personnel access authorizations.

§ 25.19 Processing applications.

45 FR 14476

Each application for access authorization together with its accompanying fee shall be submitted to the NRC Division of Security. If necessary the NRC Division of Security may obtain approval from the appropriate Commission office exercising licensing or regulatory authority before processing the access authorization request.

If the applicant is disapproved for processing, the NRC Division of Security will notify the submitter in writing and will return the original application (security packet) and its accompanying fee.

§ 25.21 Determination of initial and continued eligibility for access authorization.

(a) Following receipt by the NRC Division of Security of the reports of the personnel security investigations, the record will be reviewed to determine that granting an access authorization will not endanger the common defense and security and is clearly consistent with the national interest. If such a determination is made, access authorization will be granted. Questions as to initial eligibility, and any subsequent developments that raise a question of continued eligibility for access authorization will be determined in accordance with Part 10 of Chapter I.

(b) The NRC Division of Security shall be promptly notified of developments which bear on continued eligibility for access authorization throughout the period for which the authorization is active (e.g., persons who marry subsequent to the completion of a personnel security packet must report this change by submitting a completed form entitled "Data Report on Spouse").

§ 25.23 Notification of grant of access authorization.

The determination to grant access authorization will be furnished in writing to the licensee or organization which initiated the request. Records of these notifications must be maintained by the licensee or requesting organization for one year after the access authorization has been terminated by the NRC Division of Security. This information may also be furnished to other representatives of the Commission, to licensees, contractors, or other Federal agencies. Notifications of access authorization will not be given in writing to the individual himself except:

(a) In those cases in which the determination was made as a result of a Personnel Security Board or a Personnel Security Review Board hearing, or

(b) When the individual also is the official designated by the licensee to whom written NRC notifications are forwarded.

§ 25.25 Cancellation of requests for access authorization.

When a request for an individual's access authorization is withdrawn or cancelled, the NRC Division of Security will be notified by the requestor immediately by telephone so that the full field investigation or National Agency Check may be discontinued. The caller will supply the full name and date of birth of the individual, the date of request, and the type of access authorization originally requested ("Q" or "L"). Such telephone notice shall be promptly confirmed in writing.

45 FR 14476

§ 25.27 Reopening of cases in which requests for access authorizations are cancelled.

(a) In conjunction with a new request for access authorization for individuals whose cases were previously cancelled, new fingerprint cards in duplicate and a new Security Acknowledgment shall be furnished to the NRC Division of Security along with the request.

(b) Additionally, if six months or more have elapsed since the date of the last Personnel Security Questionnaire, a complete personnel security packet (see § 25.17 (c)) shall be executed by the individual. The NRC Division of Security, based on investigative or other needs, may require a complete personnel security packet in other cases as well. A fee, equal to the amount paid for an initial request, will be charged only if a new or updating investigation is required.

§ 25.29 Reinstatement of access authorization.

An up-to-date personnel security packet will be furnished with a request for reinstatement of an access authorization if 6 months or more have elapsed since termination of access authorization and a year or more has elapsed since the date of the previous Personnel Security Questionnaire, or if any significant changes are known to have occurred since the termination. A new Security Acknowledgment will be obtained in all cases. Where personnel security packets are not required, a request for reinstatement shall state the level of access authorization to be reinstated and the full name and date of birth of the individual in order to establish positive identification. A fee, equal to the amount paid for an initial request, will be charged only if a new or updating investigation is required.

§ 25.31 Extensions and transfers of access authorizations.

(a) The NRC Division of Security may, on request, extend the authorization of an individual who possesses an access authorization in connection with a particular employer or activity, to permit access to National Security Information and/or Restricted Data in connection with an assignment with another employer or activity.

45 FR 14476

(b) The NRC Division of Security may, on request, transfer an access authorization when an individual's access authorization under one employer or activity is terminated, simultaneously with the individual being granted access authorization for another employer or activity.

48 FR 24318

(c) Requests for extension or transfer of access authorization shall state the full name of the person, his date of birth and level of access authorization. The Director, Division of Security, may require a new personnel security packet (see § 25.17(c)) to be completed by the applicant. A fee, equal to the amount paid for an initial request, will be charged only if a new or updating investigation is required.

45 FR 14476

§ 25.33 Termination of access authorizations.

(a) Access authorizations will be terminated when:

(1) Access authorization is no longer required, or

(2) An individual is separated from the employment or the activity for which he obtained an access authorization for a period of 90 days or more, or

(3) An individual, pursuant to 10 CFR Part 10, is no longer eligible for access authorization.

(b) A representative of the licensee or other organization which employs the individual whose access authorization will be terminated shall immediately notify the NRC Division of Security when the circumstances noted in paragraphs (a)(1) or (a)(2) of this section exist; inform the individual that his access authorization is being terminated, and the reason; and that he will be considered for reinstatement of access authorization if he resumes work requiring it.

(c) When an access authorization is to be terminated, a representative of the licensee or other organization shall conduct a security termination briefing of the individual involved, explain the Security Termination Statement (NRC Form 136) and have the individual complete the form. The representative shall promptly forward the original copy of the completed Security Termination Statement to the NRC Division of Security, Office of Administration, Washington, DC 20555.

48 FR 24318

Classified Visits

§ 25.35 Classified visits.

Visits to NRC, NRC contractor, licensee or licensee related facilities, or other government agencies or their contractors involving access to classified information by individuals covered by this part require advance certification of "need-to-know" and verification of NRC access authorization. Individuals planning these visits shall complete NRC Form 277, "Request for Visit or Access Approval," with the "need-to-know" certified by the appropriate NRC office exercising licensing or regulatory authority. This NRC office shall then forward the request to the NRC Division of Security at least 15 days in advance of the date of the visit for appropriate verification of NRC access authorization. The Division of Security shall forward the form to the facility to be visited. Records related to these visits must be maintained by the facility for two years following the expiration date of the visit authorization.

48 FR 24318

Violations

§ 25.37 Violations.

(a) An injunction or other court order may be obtained to prohibit a violation of any provision of:

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

48 FR 24318

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(3) Any regulation or order issued under these Acts.

(b) National Security Information is protected under the requirements and sanctions of Executive Order 12356.

(c) Whoever willfully violates, attempts to violate, or conspires to violate, any provision of the Atomic Energy Act of 1954, as amended, for which no criminal penalty is specifically provided or any regulation or order prescribed or issued under subsections 161 i or o of the Act may be guilty of a crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law. Regulations issued under the Act include regulations issued under subsections 161 i and o and cited within the authority citation at the beginning of this part for the purposes of section 223.

49 FR 32171

APPENDIX A—FEES FOR NRC ACCESS AUTHORIZATION

Category	Fee
Initial "L" Access Authorization	$15
Reinstatement of "L" Access Authorization	[1] 15
Extension or Transfer of "L" Access Authorization	[1] 15
Initial "Q" Access Authorization	1,580
Reinstatement of "Q" Access Authorization	[1] 1,580
Extension or Transfer of "Q"	[1] 1,580

[1] Full fee will only be charged if investigation is required.

PART 25

ACCESS AUTHORIZATION FOR LICENSEE PERSONNEL

PROPOSED RULE MAKING

➤50 FR 10064
Published 3/13/85
Comment period expires 5/13/85.

10 CFR Parts 25 and 95

Access to and Protection of National Security Information and Restricted Data

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations to incorporate a recently approved exception to the personnel security background investigation requirement for access to certain Communications Security (COMSEC) information; to provide a procedure to ensure that licensees obtain prior NRC approval to effect any substantive changes to a licensee's security plan; and to adopt several revisions that are strictly ministerial in nature. These proposed actions are intended to revise the regulations to reflect current agency policy and practice and to make clarifications to the regulations that past agency experience indicates are necessary.

DATE: Submit comments by May 13, 1985. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

ADDRESSES:

Send comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC, 20555. ATTN: Docketing and Service Branch.

Hand deliver comments to: Room 1121, 1717 H Street, NW, Washington, DC between 8:15 a.m. and 5:00 p.m.

FOR FURTHER INFORMATION CONTACT:
Richard A. Dopp, Chief, Policy and Operational Support Branch, Division of Security, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 427-4548

SUPPLEMENTARY INFORMATION: The National Communications Security Committee (NCSC) has recently granted NRC an exception to personnel security background investigation requirements relating to access by certain NRC licensee individuals to Communications Security (COMSEC) information. This exemption was granted in accordance with Section IV of NCSC-2, "National Policy on Release of Communications Security Information to U.S. Contractors and Other U.S. Nongovernmental Sources," and exempts NRC licensee facility security officers from the requirement of having a full field background investigation, current within five years, as a precondition for access to COMSEC information. All NRC licensee individuals involved currently have and will continue to possess, as a minimum, an NRC-granted "L" access authorization based on a National Agency Check (NAC) background investigation. The COMSEC information to which NRC licensee personnel may need access is limited to Confidential-National Security Information material. This exemption will be limited to fewer than ten NRC licensee and other facilities, and is based, in part, on the level of classification involved (Confidential), the short duration of classification normally experienced, and the lack of impact on other government communications. In order to implement this exception, revisions to current regulations are necessary. Specifically, the current § 25.15 and § 95.35 state that an NRC "Q" access authorization is required as a precondition for access to COMSEC information. These sections are amended to reflect that an NRC "L" access authorization is sufficient for access to COMSEC information of the level and type specifically referenced by the recent NCSC exemption decision.

In a separate matter, the NRC staff has recently recognized a need to revise its regulations to better provide for changing security conditions at approved NRC security facilities covered by Part 95. The proposed new procedure is intended to clarify NRC policy by acknowledging that certain activities planned by the licensee at a security facility (e.g., remodeling or renovation of offices, moving NRC interests from one room or building to another) require advance NRC approval. NRC proposes to add a new section to provide a procedure whereby the licensee would seek the advance approval of the NRC regarding any proposed substantive changes to the name, location, security procedures and controls, or floor plan of the security facility. The current § 95.15(d) allows the licensee to make a change in an NRC approved security plan for the safeguarding of National Security Information and/or Restricted Data without prior NRC approval, provided the change does not decrease the effectiveness of the plan. NRC staff is concerned that this section may not be sufficiently precise. Specifically, whether or not a change contemplated by a licensee to a security plan decreases the plans effectiveness is highly subjective. NRC staff believes that § 95.15(d) be deleted in favor of a new § 95.18, which sets forth, in greater detail, the circumstances under which licensees may make changes to the name, location, security procedures and controls, and/or floor plan of the approved security facility. The proposed new § 95.18(a) outlines a procedure whereby the licensee would require advance NRC approval prior to adopting revisions to the minimum security conditions upon which facility approval had originally been granted. A new § 95.18(b) now prescribes in greater detail those changes to security operations not requiring advance NRC approval but requiring prompt notification by the licensee. This proposed revision is intended to better ensure that changing conditions at a security facility, potentially impacting the protection of National Security Information and/or Restricted Data, are brought to the attention of NRC far enough in advance to provide a better opportunity to review and resolve them and avoid a situation which could affect continuing security facility approval.

Finally, NRC staff has identified several revisions that are generally ministerial in nature which should clarify and improve the effectiveness and accuracy of 10 CFR Parts 25 and 95.

Environmental Impact: Categorical Exclusion

The NRC has determined that this proposed regulation is the type of action described in categorical exclusion 10 CFR 51.22(c)(1). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this proposed regulation.

Paperwork Reduction Act Statement

This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). This rule has been submitted to the Office of Management and Budget for review and approval of the paperwork requirements.

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. Each NRC licensee or other organization which may require access to National Security Information and/or Restricted Data in connection with a license or application for a license will be impacted by this proposed rule. Only 12 entities (which include five fuel-cycle facilities, three transportation companies, one reactor and three other organizations) are currently required to meet the requirements of 10 CFR Parts 25 and 95. Since none of these has been determined to be small as defined by the Regulatory Flexibility Act of 1980, the Commission finds that this rule will not have a significant economic impact upon a substantial number of small entities.

List of Subjects

10 CFR Part 25

Classified information, Investigations, Penalty, Reporting and recordkeeping requirements, Security measures.

10 CFR Part 95

Classified information, Penalty, Reporting and recordkeeping requirements, Security measures.

Under the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, the Independent Offices Appropriation Act of 1952 and 5 U.S.C. 553, the NRC is proposing to adopt the following amendments to 10 CFR Parts 25 and 95.

PART 25—ACCESS AUTHORIZATION FOR LICENSEE PERSONNEL

1. The authority citation for Part 25 continues to read as follows:

Authority: Secs. 145, 161, 68 Stat. 942, 948, as amended (42 U.S.C. 2165, 2201); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); E.O. 10865, as amended, 3 CFR 1959–1963 COMP., p. 398 (50 U.S.C. 401, note); E.O. 12356, 47 FR 14874, April 6, 1983.

Appendix A also issued under 96 Stat. 1051 (31.U.S.C. 9701).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273), §§ 25.13, 25.17(a), 25.33 (b) and (c) are issued under sec. 161i, 68 Stat. 949, as amended (42 U.S.C. 2201(i)); and §§ 25.13 and 25.33(b) are also issued under sec. 161o, 68 STat. 950, as amended (42 U.S.C. 2201(o)).

2. In § 25.5, the definition of "L" access authorization is revised to read as follows:

§ 25.5 Definitions.

* * * * *

"L" access authorization means an access authorization granted by the Commission which is normally based on a National Agency Check (NAC) or NAC and Inquiries (NACI) conducted by the Office of Personnel Management.

* * * * *

3. In § 25.15, paragraph (b) is revised to read as follows:

§ 25.15 Access permitted under "Q" or "L" access authorization.

* * * * *

(b) An "L" access authorization permits an individual access on a need-to-know basis to Confidential Restricted Data and Secret and Confidential National Security Information other than the categories specifically included in paragraph (a) of this section. In addition, access to certain Confidential COMSEC information is permitted as authorized by a National Communications Security Committee waiver dated February 14, 1984.

* * * * *

PART 95—SECURITY FACILITY APPROVAL AND SAFEGUARDING OF NATIONAL SECURITY INFORMATION AND RESTRICTED DATA

4. The authority citation of Part 95 continues to read as follows:

Authority: Secs. 145, 161, 68 Stat. 942, 948, as amended (42 U.S.C. 2165, 2201); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); E.O. 10865, as amended, 3 CFR 1959–1963 COMP., p. 398 (50 U.S.C. 401, note); E.O. 12356, 47 FR 14874, April 6 1982.

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 95.13, 95.15(a), 95.25, 95.27, 95.29(b), 95.31, 95.33, 95.35, 95.37, 95.39, 95.41, 95.43, 95.45, 95.47, 95.51, 95.53, and 95.57 are also issued under sec. 161i, 68 Stat. 949, as amended (42 U.S.C. 2201(i)).

5. In § 95.5, the definitions of "Authorized Classifer," "Infraction" and "L" access authorization are revised to read as follows:

§ 95.5 Definitions.

* * * * *

"Authorized Classifier" means an individual authorized in writing by appropriate authority to classify, declassify or downgrade the classification of information. This term applies to authorized derivative classifiers and authorized original classifiers.

* * * * *

"Infraction" means an act or omission involving failure to comply with NRC security requirements or procedures.

* * * * *

"L" access authorization means an access authorization granted by the Commission which is normally based on a National Agency Check (NAC) or NAC and Inquiries (NACI) conducted by the Office of Personnel Management.

* * * * *

§ 95.15 [Amended]

6. In § 95.15, paragraph (d) is removed.

7. A new § 95.18 is added to read as follows:

§ 95.18 Changes to security practices and procedures.

(a) Except as specified in paragraph (b) of this section, each licensee or other person shall obtain prior NRC approval for any proposed change to the name, location, security procedures and controls, or floor plan of the approved facility. A written description of the proposed change must be furnished to the NRC Director, Division of Security, Office of Administration, Washington, D.C. 20555, with a copy of the Regional Administrator of the cognizant Regional Office listed in Appendix A of Part 73. The NRC shall promptly respond in writing to all such proposals. Some examples of substantive changes requiring prior NRC approval include:

(1) A change in the approved facility's classified mail address; or

(2) A temporary or permanent change in the location of the approved facility (e.g., moving or relocating NRC's classified interest from one room or building to another).

(b) A licensee or other person may affect a minor, nonsubstantive change to an NRC approved facility security plan for the safeguarding of National Security Information and/or Restricted Data without receiving prior NRC approval provided prompt notification of such minor change is furnished to the addressee noted in paragraph (a) of this section, and the change does not decrease the effectiveness of the plan. Some examples of minor, nonsubstantive changes to the facility security plan include:

(1) The designation/appointment of a new facility security officer; or

(2) A revision to protective personnel patrol routine, provided the new routine continues to meet the minimum requirements of this part.

8. Section 95.19 is revised to read as follows:

§ 95.19 Grant, denial or termination of security facility approval.

The Division of Security shall provide notification in writing (or orally with written confirmation) to the licensee or other organization, of the Commission's grant, denial, or termination of security facility approval. This information shall also be furnished to representatives of NRC, NRC licensees, NRC contractors, or other Federal agencies having a need to transmit National Security Information and/or Restricted Data to the licensee or other person.

9. In § 95.21, the heading is revised to read as follows:

§ 95.21 Withdrawal of requests for security facility approval.

* * * * *

10. The heading of § 95.25 is revised to read as follows:

§ 95.25 Protection of National Security Information and Restricted Data in storage.

11. Section 95.27 is revised to read as follows:

§ 95.27 Protection while in use.

While in use, matter containing National Security Information or Restricted Data must be under the direct control of an authorized individual to preclude physical, audio and visual access by persons who do not have the prescribed access authorization or other written Division of Security disclosure authorization (see § 95.36 for additional information concerning disclosure authorizations).

12. The heading of § 95.35 and paragraph (a)(1) are revised to read as follows:

§ 95.35 Access to National Security Information and Restricted Data.

(a) * * *

(1)(i) A "Q" access authorization which permits an individual access to (A) Secret and Confidential Restricted Data and (B) Secret and Confidential National Security Information which includes intelligence information, CRYPTO (i.e., cryptographic information) or other classified communications security (COMSEC) information, or

(ii) An "L" access authorization which permits an individual access to Confidential Restricted Data and Secret and Confidential National Security Information other than that noted in paragraph (a)(1)(i) of this section except that, access to certain Confidential COMSEC information is permitted as authorized by a National Communications Security Committee waiver dated February 14, 1984.

* * * * *

13. In § 95.41, the heading is revised to read as follows:

§ 95.41 Accountability for Secret matter.

* * * * *

14. In § 95.53 the heading and paragraph (b) are revised to read as follows:

§ 95.53 Termination of security facility approval.

* * * * *

(b) In any instance where security facilty approval has been terminated based on a determination of the Commission that further possession of classified matter by the facility would not be in the interest of the national security, the facility shall, upon notice from the Commission, immediately deliver all classified documents and materials to the Commission along with a certificate of nonpossession of National Security Information and Restricted Data.

15. Section 95.55 is revised to read as follows:

§ 95.55 Continued applicability of the regulations in this part.

The suspension, revocation or other termiantion of access authorization or the termination of security facility approval shall not relieve any person from compliance with the regulations in this part.

16. Section 95.59 is revised to read as follows:

§ 95.59 Inspections.

The Commission shall make inspections and surveys of the premises, activities, records and procedures of any person subject to the regulations in this part as the Commission deems necessary to effect the purposes of the Act, E.O. 12356 and/or NRC rules.

Dated at Bethesda, MD, this 15th day of February 1985.

For the Nuclear Regulatory Commission.

William J. Dircks,

Executive Director for Operations.

PART 25

ACCESS AUTHORIZATION FOR LICENSEE PERSONNEL

STATEMENTS OF CONSIDERATION

45 FR 14476
Published 3/5/80
Effective 5/19/80
(Effective date extended to 10/1/80)

10 CFR Parts 25 and 95

Access to and Protection of National Security Information and Restricted Data

AGENCY: Nuclear Regulatory Commission (NRC).

ACTION: Final rules.

SUMMARY: The Nuclear Regulatory Commission has issued proposed rules governing access to and protection of National Security Information and Restricted Data. When former Atomic Energy Commission regulations were reissued in March 1975 by the Nuclear Regulatory Commission, rules governing access to and protection of the National Security Information and Restricted Data were not included. A joint Energy Research and Development Administration-Nuclear Regulatory Commission task force was formed on March 17, 1976, to propose a plan of action for improving the control and protection of nuclear materials at NRC-licensed fuel cycle facilities. The task force addressed the current status and future direction of physical security protection at NRC-licensed facilities possessing formula quantities of strategic special nuclear materials. These rules establish procedures to facilitate licensee access to and protection of National Security Information and Restricted Data.

EFFECTIVE DATE: These rules become effective May 19, 1980.

Note.—The Nuclear Regulatory Commission has submitted these rules to the Comptroller General for such reviews as may be appropriate under the Federal Reports Act, as amended, 44 U.S.C. 3512. The date on which the reporting requirements of these rules become effective, unless advised to the contrary, accordingly reflects inclusion of the 45-day period which that statute allows for such review (44 U.S.C. 3512(c)(2)).

FOR FURTHER INFORMATION CONTACT: Mr. Raymond J. Brady, Director, Division of Security, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, (301) 427–4472.

SUPPLEMENTARY INFORMATION: In the July 2, 1979 issue of the **Federal Register** (44 FR 38533), the Nuclear Regulatory Commission published a notice of proposed rulemaking establishing procedures to facilitate licensee access to and protection of National Security Information and Restricted Data.

Interested persons were given until August 31, 1979, to submit written comments regarding the proposed rule. All comments received were carefully considered. Written comments received pursuant to that notice are available at the NRC's Public Document Room, 1717 H Street, NW., Washington, DC 20555, (301) 634–3273.

Summary of Comments Received and Responses

The following comments resulted in changes to the proposed rules and have been incorporated into the final versions:

One commenter did not understand why in §§ 25.13 and 95.13, only certain records concerning personnel security access authorizations and security facility approvals were subject to review and inspection during security surveys. The suggestion to delete the words "certain of" from each section was adopted.

One commenter indicated that § 25.21 did not establish a time frame for notification of developments which bear on continued eligibility for access authorization. A revision has been made which inserted the word "promptly" between the words "be" and "notified."

One commenter suggested that the 60-day period mentioned in § 25.33(a)(2) is excessively short and should be, as a minimum, extended to 90 days. The suggestion to extend this period to 90 days has been adopted.

One commenter suggested that the definition of "Combination Lock," § 95.5, be more precise and offered "The lock shall meet the Group 1 or Group IR combination lock requirement of UL Publication No. 768." The suggestion to modify the definition of "combination lock" has been adopted.

One commenter suggested that the alarming requirements for a "vault-type room," § 95.5, appeared excessive compared to the consequence of theft and further asked whether valid entries were meant to generate alarms. The definition of vault-type room has been changed to: A vault-type room is one that has a combination lock door and is protected by an intrusion alarm system which alarms upon the unauthorized penetration of a person anywhere into the room.

One commenter indicated it was his understanding relative to § 95.25(i), that "containers" will have combination locks, not keys. The following phrase was deleted "* * * on containers holding classified matter or * * *"

One commenter on § 95.37(i) advised that the Information Security Oversight Office (ISOO) Directive No. 1, Section V, requires that anonymity of the challenger of the propriety of a given classification be preserved on request. A revision of this section, which added the following sentence after the first complete sentence, has been made: "Whenever requested, this challenge of classification marking shall be handled in a manner which will assure the anonymity of the challenger."

One commenter found the tone of § 95.59, "The Commission *may* make such inspections and surveys of the premises, activities * * *" too permissive. The commenter believed security inspections should be conducted on a recurring basis for all cleared licensed facilities handling classified material to ensure compliance with the Atomic Energy Act of 1954, as amended, E.O. 12065, and the Commission's rules. The commenter also offered his thoughts on the purposes for and the benefits received from such inspections. This section was revised as follows: "The Commission *shall* make inspections and surveys * * * to effect the purposes of the Act, E.O. 12065, and Commission rules." NRC procedures provide for recurring periodic surveys for the very purposes mentioned by the commenter.

As a result of further review by the NRC staff, the following significant change was also made: In § 95.37(a) the following statement was added: "Such marking of information shall be in compliance with NRC classification guidance found in the NRC Classification Guide for Safeguards Information, Appendix A of this part.

In addition to the comments that resulted in changes in the proposed rules, a number of other issues were raised which resulted in no changes but which warrant discussion and explanation as follows:

One commenter noted, relative to § 25.17 (b and c), that if the NRC is going to accept the investigations and reports of other Federal Government agencies in lieu of complete new investigations for current access authorization holders, then the submittal of an abbreviated personnel security packet should be permitted to reduce the burden and cost of supplying a packet as outlined in this section. The NRC may accept the investigations and reports of other Federal Government agencies for current access authorization holders whenever the investigation is five years old or less and the scope of the investigation meets the criteria for the level of clearance requested. Individuals failing within this category will be granted an NRC access authorization providing no unresolved derogatory information has been added to their existing security file and no questionable information is contained in the security packet which they submit. If an access authorized individual's last investigation is more than five years old, a determination in accordance with accepted personnel security procedures will be made as to whether any supplemental investigation is necessary. While revisions to various forms are contemplated, a standard NRC security packet consists of the forms outlined in § 25.17(c). This standard packet is being requested from each individual to avoid the confusion inherent in having an individual attempt to determine which set of forms to complete. This will also eliminate any need for going back to an individual a second time for additional information. It has been estimated that approximately 1.5 to 2.0 hours would be required to complete this standard forms packet.

One commenter recommended that the term "immediately" in § 25.33(b) and the term "promptly" in § 25.33(c) be defined. These two terms are used throughout NRC's management directives applicable to direct NRC employees and NRC contractors handling classified information. In each case, notification should occur within one or two working days of the incident which precipitates the notification action. Since other events and tasks, perhaps of higher priority, would prevent immediate notification, it is NRC's intention not to prescribe a requirement which the licensee may violate due to circumstances beyond his control.

Two commenters recommended that § 25.37 include procedures to provide for visits with much shorter than 15-day notification periods to cover unusual situations and for multiple visits within an extended period of time. Certain facilities outside of NRC's control require the 15-day notification. Emergency procedures exist in some areas which provide for visits with a shorter than 15-day notification period. When such advance notice is not possible, but the NRC Form 277 has been received by the Division of Security, the visit may be processed telephonically. However, telephonic notifications of visits increase the probability of errors and the likelihood that the visit request will not be properly processed. Additionally, it increases the administrative effort of all concerned in the processing of the visit. These procedures, and others which provide for multiple visits within an extended period of time, will be covered in more detail in an NRC regulatory guide for protection of classified information and matter which is currently being written.

One commenter believed the scope of Part 95 as reflected in § 95.3 and the application of Part 95 as defined in § 95.15(a) are potentially enormous in breadth and urged that the regulations more specifically identify the kinds of persons affected and at what stage in the licensing process they become subject to the Parts. The emphasis or direction of the scope described in § 95.3 is aimed at those individuals who require access to NRC classified information, either National Security Information or Restricted Data. If this "need-to-know" principle has been established, and if personnel at a facility need to use, process, store, reproduce, transmit or handle classified information, then Part 95 provides the mechanism by which the facility can be approved by NRC to meet these needs. NRC will not attempt to apply these provisions "across-the-board" to all licensees and others regulated by the Commission, but rather will (1) respond to a request from those indicating a future need for access to NRC classified information and (2) request those who will possess NRC classified information (based on the new NRC safeguards classification guide) to adhere to the provisions of this part. It is estimated this latter area (i.e., those facilities possessing nonself-protecting formula quantities of SSNM) includes approximately sixteen facilities (light water reactors are not included within the scope of the classification guide).

The words "* * * licensee, or other person who has a need * * * in connection with Commission related activities * * *" in 95.15(a) is purposefully broad to permit the justifiable application of this Part to other support businesses or facilities (i.e., a licensee contractor) which may not be licensed by NRC, but which require access to NRC classified information. The provisions of this Part become applicable when, and only when, the licensee or other activity has indicated a need to use, process, store, reproduce, transmit or handle NRC classified information.

One commenter recommended that the definition of a safe, § 95.5, be written to comply with the publication of new UL specifications scheduled to be effective on January 31, 1980, indicating that new specifications will provide for "equivalent" resistance to steel. Most all facilities affected by these parts currently possess security containers as defined in § 95.5 and will be able to comply with its provisions. Section 95.5 provides for the use of other repositories, such as those noted by the commenter, which in the judgment of the Division of Security would provide comparable physical protection.

One commenter recommended that the terms "immediately" and "promptly" in § 95.21 be defined. The discussion above relative to § 25.33 applies here.

One commenter suggested that the requirement for NRC approval of intrusion alarms as reflected in § 95.25(a)(1) seemed unnecessary. Since alarm systems vary in quality and efficiency over an enormous range, NRC reserves the right to ensure the system is adequate.

One commenter pointed out that § 95.25(h) seemed to require a report to the NRC every time an unattended security container is found open and, similarly, that § 95.57 required that all "infractions" (defined to mean acts or omissions involving failure to comply with NRC security regulations) be "immediately" reported to NRC. This commenter and one other believed it was imperative that some kind of "rule of reason" be incorporated into the proposed regulations to avoid the suffocation in an ocean of paper resulting from minor infractions where security is not breached. Minor or major security infractions will not occur frequently if affected individuals and facilities adhere to proper security procedures. If those individuals affected by these Parts frequently leave safes open, leave documents unattended, or allow unauthorized access to classified information. NRC certainly wants to be aware of the situation and circumstances. These same reporting requirements apply to NRC Headquarters and Regional Offices as well as all other NRC contractors which handle NRC classified information. Experience has shown this does not result in unmanageable or burdensome reporting or paperwork.

One commenter questioned why individuals authorized access to a security area (§ 95.29) shall be issued a badge *only* "when the number of employees assigned to the area exceeds 30 per shift" and desired to know the rationale for not issuing badges to *all* such individuals. It has been NRC's experience that less than 30 individuals per shift requiring access to a security area can be physically recognized and identified by the individual controlling access. A printed roster of 30 individuals or less has proven to be an efficient and effective control device. The manufacturing cost of 30 or less unique identification badges or the alteration of existing plant or company badges would be burdensome. The provisions, as stated, conform to approved existing procedures relative to NRC contractor classified operations.

Relative to § 95.33, one commenter noted that the security education program should include alerting participants to the dangers of sabotage and espionage and to suggest preventive measures which a licensee may adopt to avoid such dangers. This commenter specifically asked whether NRC provided guidance for the security education program established and maintained by the licensee and whether the final program was subject to NRC approval. The NRC Division of Security will provide guidance for licensee security education programs.

Items such as those mentioned by the commenter shall be incorporated into their programs. An NRC regulatory guide for the protection of classified information and matter which identifies these elements of a good security education program is being prepared for licensees. A licensee's security education program and the records maintained to support it are reviewed and subject to NRC approval.

One commenter believed that more detail and guidance were needed concerning the handling and classification of material originated by licensees and applicants. He further suggested that the procedure for classification described in 95.37 would require much additional correspondence if implemented as written, and would be very time-consuming and inefficient. This commenter who is not affected by these Parts misunderstood the definition and application of the term "Restricted Data." He mistakenly believed his facility possessed large amounts of such material. True, if he or his facility were affected, it would result in additional correspondence, but not to the extent it would be time-consuming and inefficient. A licensee official may be an NRC authorized derivative classifier. This would eliminate much of the required correspondence. The handling and classification procedures parallel the Department of Energy (DOE) procedures covering such material. Additionally, a safeguards classification guide, Appendix A of Part 95, and an NRC regulatory guide for the protection of classified information and matter will provide most of any additional detail and guidance which may be necessary.

Another commenter, addressing § 95.37, believed this section would require, or at least authorize, classification markings, at variance with those required by the DOE under 10 CFR 795.32 (although they appear to be consistent with DOE's Appendix 2105). He believed this raised the possibility that certain documents subject to Part 95 might have two sets of classification stamps applied to them. Since the DOE's and NRC's Restricted Data handling and classification procedures are consistent or the same, there should be no variance in the application of markings and classification stamps in this area. Since, however, DOE's Part 795 pertains only to Restricted Data, while NRC's Part 95 pertains to Restricted Data and *National Security Information*, there are additional authorized classification markings for this type of information. These markings are not at variance with, but are in lieu of or in addition to, the markings for Restricted Data.

One commenter noted that the classification marking required by § 95.37(e)(2) is not provided for in Executive Order 12065. The commenter stated that this marking (required under the former Order) was eliminated from E.O. 12065 because it was considered superfluous. The NRC Division of Security recognizes that E.O. 12065 does not provide for this marking. However, it conversely does not preclude its use. Based on NRC Manual Chapter and Appendix 2101, Part III and NRC Bulletin 2101-11, this marking has been, and is being, used within the NRC. It is necessary to maintain consistency between Part 95's application and internal NRC classification procedures and markings. Therefore, no revision or change is recommended for this section.

One commenter did not understand the meaning in § 95.39(b)(3) of the expression "that the outer envelope * * * shall contain the addressee's *classified* mail address." The commenter believed this was a typographical error since no classified information shall be affixed to the outer envelope. The commenter misunderstood the definition of "classified mail address" as found in § 95.5 which indicates this is an address to which classified information (contained in an inner envelope) may be sent. The address itself is not classified, but represents a location, approved by NRC, to which classified information can be sent with the assurance that it will be received by properly cleared individuals.

Two commenters felt the provision of § 95.57 to submit a report whenever a classified document was generated, destroyed or had its classification changed was unnecessary. One of the two commenters did not believe the distinction among "originated," "generated," and "reproduced" was clear. More specifically, this commenter was uncertain whether a document would be "generated" for the purposes of § 95.57 if it were derived from information made available to them under the Access Permit Program administered by DOE. The requirements to submit a report whenever a classified document is generated, destroyed or has its classification changed stems from Section 5-202(h) of Executive Order 12065. Through this Section, the Information Security Oversight Office (ISOO), GSA has identified the minimum data necessary to fulfill its oversight responsibility of ensuring effective implementation of the Government's information security program. It also uses such data to keep the President informed on the status of the implementation of E.O. 12065. Such reports and records must be forwarded to NRC from those affected by Part 95 in order to fulfill this requirement. NRC in turn consolidates these reports and forwards data to ISOO. These reports also serve as the basis for NRC's own classification appraisals required by NRC management directives. Although only the word "generated" is used in § 95.59, the words "generated" and "originated" are synonymous. They are used to indicate papers or documents which are newly prepared, written or created; papers or documents which did not previously exist in that form. "Reproduce" means a physical duplication or exact copy of papers or documents which were previously "generated" or "originated." It may be possible for a document to be "generated" or "originated" for the purposes of Part 95, which is derived

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from Restricted Data available under DOE's Access Permit Program. In such cases, information as required by NRC Form 790, in accordance with § 95.57, shall be forwarded to the NRC Division of Security.

One commenter believed that the programs detailed in Part 95 represented an extreme and, in most cases, an unnecessary increase in the level of protection afforded Restricted Data associated with commercial, nuclear-powered electrical generating facilities and that the recommended protection was comparable to that given to Department of Defense "Secret" material (a disclosure of which, in the eyes of the commenter, would result in a much greater danger than disclosure of "Restricted Data" associated with nuclear powerplants). The commenter also believes that nearly everyone assigned to a plant or involved with its design would require a clearance, thus creating a logjam of clearance requests, requests for facility approvals and requests for classification of material.

Parts 25 and 95 specifically apply to less than twenty NRC-licensed facilities which possess nonself-protecting formula quantities of SSNM since information relative to the protection of such material is covered within the classification guide. These parts do not routinely apply to normal commercial, light water reactor facilities unless such facilities otherwise specifically request personnel and facility clearances based on a need to store or handle other NRC classified information. This application should not result in a logjam of requests for personnel clearances, facility approvals or classification guidance. These Parts are, in fact, aimed at providing protection comparable to that given to Department of Defense "Secret" material since they do address classified information (National Security Information and Restricted Data). This commenter's view of Restricted Data, however, differs from that defined in the Atomic Energy Act of 1954, as amended, and as used in Parts 25 and 95. This commenter incorrectly viewed Parts 25 and 95 as being applicable to his facility.

One commenter, while recognizing that both the DOE and NRC have responsibility to control the dissemination of Restricted Data in the interest of the common defense and security, pointed out that DOE has the sole responsibility to establish the "basic standards and procedures." The commenter believed that the proposed rules largely ignored the existence of DOE's "basic standards and procedures" and DOE's regulations covering Restricted Data in the hands of DOE contractors and Access Permittees. Except for minor differences, NRC's procedures are consistent with DOE's "basic standards and procedures" covering personnel and facility clearances. DOE's Part 795 applies to persons who receive access to Restricted Data (RD) or develop Restricted Data under the Access Permit Program. Parts 25 and 95 are broader in scope in that they apply to persons who require access to Restricted Data and/or *National Security Information (NSI).* NRC recognizes DOE's interest in protecting Restricted Data, but does not relinquish its own required regulation and control of NRC Restricted Data and NSI.

One commenter stated that licensees and license applicants must be informed of the rules for determining what information they (licensees and applicants) develop might be considered classified by NRC. This commenter believed that a separate rulemaking was necessary to determine the procedures to be followed in classifying information which might be subject to the provisions of Parts 25 and 95. Two items prepared by NRC will help in this area; one, an NRC safeguards classification guide which specifically identifies the elements of information which will be classified; and two, a soon to be published NRC regulatory guide for the protection of classified information and matter.

One commenter asked whether a putative license applicant is subject to Part 95 in the early stages of its planning, long before a license application is drafted. If a license applicant can determine, or is aware, very early in the license application development, that his facility will maintain formula quantities of SSNM, he should be aware of the possibility that certain safeguards information he develops may be classified. If his facility will maintain formula quantities of SSNM, he may originate or need access to classified information very early in the facility design stage. If he can effectively rule out the requirement to safeguard formula quantities of SSNM and has no other need for access to classified information, he need not concern himself with the requirements of Parts 25 and 95.

One commenter asked whether suppliers and consultants of licensees are subject to Part 95 and if they are, when they become subject. Suppliers, consultants, and licensee contractors may be subject to Parts 25 and 95 if they, as individuals, require access to NRC classified information (as identified in the NRC classification guide) or if they need to use, store, handle, etc., classified information at their offices or facilities. They would become subject to these rules when the need for access to classified information has been established by the NRC.

One commenter noted they are now subject to DOE's Part 795 and could not perceive why NRC cannot adopt as its own, the precise language of 10 CFR Part 795. NRC's language and requirements covering Restricted Data (RD) in Part 95 are consistent with and, in fact, very similar to those in DOE's Part 795. The major differences in these two Parts stem from the broader coverage of Part 95 to include requirements governing the handling and storage of National Security Information, which based on Executive Order requirements, are somewhat different from those for RD.

One commenter noted that DOE, in 10 CFR Part 795, has reserved the authority to deny access to certain kinds of Restricted Data under the Access Permit Program, but saw no such restrictions by NRC. This resulted in his question whether a company that has not been afforded access to Restricted Data under Part 795 might be afforded such access through compliance with the NRC regulations or vice versa. Parts 25 and 95 have been prepared to facilitate access to classified information (Restricted Data and National Security Information) based upon the individual's "need-to-know." Any information which becomes classified based upon the application of the guidance provided by an NRC classification guide would be available to an individual (or individuals) providing they have the "need-to-know" and are cleared by NRC. Any information designated as RD by NRC's guide has been done so on the basis of a previous determination by DOE. Since all categories of RD in the NRC guide have already been addressed by DOE, it is highly unlikely that a licensee will have or require additional access to RD over that which he already has.

Assuming that NRC must adhere to the "basic standards and procedures" of DOE, one commenter did not understand the necessity for the apparent requirements for separate NRC access authorization determinations for a person who already has a DOE access authorization for Restricted Data. DOE's access authorization permits a licensee access to specific categories of Restricted Data (RD). This access authorization determination is made in accordance with the provisions of the Atomic Energy Act of 1954, as amended. NRC, in Part 25, applies the same "basic standards and procedures" to determine eligibility for access to RD. In addition, because additional access is involved, NRC also applies the necessary standards and procedures found in Executive Orders 12065 and 10865, governing the general provisions for handling National Security Information and the specific provisions as they relate to industry. The investigative basis for the existing DOE access authorization will be used for the NRC determination wherever possible and whenever the application of acceptable personnel security practices permit. There is no desire, nor is there any statutory method, by which NRC can relinquish its prerogative to make an independent judgement regarding eligibility for access to NRC classified information (NSI and RD). Arrangements with DOE and the Department of Defense will be made whereever possible to facilitate the common use of investigative and other security data.

One commenter advised their facility operates under rules and provisions of the DOE whose regulations cover all items addressed in Proposed Rules 10 CFR Parts 25 and 95 and that the application of these new regulations would constitute a total duplication of an already effective program for possessing and handling classified information. As a result of the NRC's decision to classify certain safeguards information through the application of E.O. 12065 and an NRC classification guide, specific licensees will now possess NRC classified information. Existing statutes and Executive Orders (Atomic Energy Act, E.O. 12065, E.O. 10865) require an agency to determine the trustworthiness of the individuals requiring access to its information and ensure that providing access will not endanger the common defense and security. There is no way for an agency to relinquish this responsibility. Granted, there may be some duplication of programs; however, since DOE's and NRC's regulations are nearly identical, it should result in a minimal cost impact to those already operating under DOE's regulations.

One commenter took exception to the joint Energy Research and Development Administration Nuclear Regulatory Commission task force conclusion that a plan for improving the control and protection of nuclear materials at NRC-licensed generating stations is necessary. The commenter felt that applicable portions of 10 CFR 2.790 and 10 CFR Part 73 provided adequate control and protection of nuclear materials and associated documentation. This commenter believed that implementation of Parts 25 and 95 would provide no significant increase in the protection of the public safety or to the national defense and did not believe that NRC-licensed facilities needed access to classified information pertinent to the protection of their facilities. In September 1978, NRC approved a plan for implementation of a classified program applicable to activities possessing significant quantities of SSNM. This approval was based on a series of decisions by the National Security Council and a determination by the President that, owing to the potential consequences of loss or diversion of significant quantities of SSNM, or sabotage of facilities or activities involving SSNM, the unauthorized disclosure of certain information relating to the protection of such materials, facilities, or activities could reasonably be expected to cause some degree of damage to the national security and, therefore, certain such information should be classified. Certain site-specific safeguards information under current NRC regulations is "deemed to be commercial or financial information" and has been withheld from public disclosure while in the hands of the NRC based on 10 CFR 2.790(d)(1). There is, however, no existing law which expressly provides that unclassified NRC sensitive safeguards information be withheld from disclosure. The two basic objectives of this program are (1) assuring the trustworthiness of persons generating and having access to the subject information and (2) protecting the information from unauthorized disclosure while in the possession of NRC.

One commenter believed that most of the documentation and activities proposed for classification are already a matter of public record in the form of licensing documents, technical papers and job specifications and that costs and manpower needed to classify and impose controls on such information cannot be justified. The material and documentation proposed for classification and thus covered by these parts relates primarily to measures for the physical protection as well as control and accounting of nuclear materials, including inventory discrepancy data. This material, once submitted to NRC is not widely disseminated, but rather is protected and handled as proprietary information. It is expected that industry has taken other steps to protect this highly sensitive information as opposed to disseminating it widely.

One commenter believed that, since licensed facilities currently perform personnel screenings prior to employment and restrict access to special nuclear material in accordance with 10 CFR 73.55, additional "clearances" or "controls" would be redundant and serve no practical purpose. A licensee's own personnel screenings and 10 CFR 73.55 controls do not fulfill the statutory-executive order requirements relative to access to, and contol over, government classified information (NSI and RD). Only the Federal Government can grant final personnel security clearances authorizing access to such information. Additionally, those facilities (i.e., licensees) which need to store, use, handle, etc., information classified by the Federal Government must adhere to the provisions as contained in Part 95.

One commenter did not believe that the NRC Division of Security should determine a licensee employee's eligibility since the individual (not employed by NRC or as an NRC contractor) is not performing work directly related to national defense contracts. If it is determined that an individual employed by a licensee requires access to NRC classified information, then *NRC*, in accordance with E.O. 12065 and the Atomic Energy Act of 1954, as amended, must determine that individual's eligibility for access.

One commenter stated that the procedures in § 25.17 and eligibility determined in § 25.21 only present a "picture in time" and do not provide a significant degree of assurance against compromise of proprietary information, and do not significantly reduce present or future threats defined in 10 CFR 73.55(a). The eligibility determined in § 25.21 using the criteria contained in 10 CFR Part 10 has been used by the NRC and its predecessor agency (Atomic Energy Commission) since 1962. (While previous similar criteria existed as early as 1950, they were not published as part of the Code of Federal Regulations until May 5, 1962.) The eligibility determination and criteria have always been based on personal historical data as well as current data. This eligibility determination is made and the criteria have been developed to specifically afford protection of and control access to classified information.

One commenter believed that the financial and administrative burdens of compliance with both § 25.17 and 10 CFR 73.55 screening requirements were unreasonable, not necessary and resulted in unwarranted distributive costs to the licensee's customers/taxpayers. Compliance with § 25.17 should be a minor financial or administrative burden within any organization which has an existing security program. The financial burden (approximately $30.00 per access authorization requested) may be less for a facility which currently has affected employees cleared by DOE or the Department of Defense. The administrative burden associated with § 25.17, including the handling, reviewing and forwarding of security forms packets between affected employees and NRC, and minor record keeping requirements, are necessary in order to provide the proper protection and control over NRC classified information. It is believed that the procedures required by § 25.17 can be incorporated into existing security procedures without unreasonable and unwarranted distributive cost to the licensee's customers.

One commenter indicated the definition of "Restricted Data," § 95.5, was not very concise, leaving much to doubt, and recommended a more detailed description. This definition of Restricted Data has been extracted verbatim from the Atomic Energy Act of 1954, as amended, and has been used and understood throughout government and industry since that time. For the most part, the majority of all Restricted Data has been originated by the DOD, DOE, NRC, and predecessor agencies. As pertains to Parts 25 and 95, very specific guidance shall be given to those facilities subject to the regulations (i.e., those prossessing more than formula quantities of nonself-protecting strategic special nuclear materials (SSNM)) as to the exact category (Restricted Data or National Security Information) and level (Confidential or Secret) of information they must protect. This particular commenter does not represent a facility which possesses nonself-protecting formula quantities of SSNM and would not be subject to the regulations unless a subsequent need arises to store and maintain NRC classified information.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganizaiton Act of 1974, as amended, and Section 552 and 553 of Title 5 of the United States Code, new Parts 25 and 95 to Title 10, Chapter I, Code of Federal Regulations, are published as a document subject to codification.

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45 FR 71763
Published 10/30/80
Effective 10/30/80

10 CFR Part 25

Access Authorization for Licensee Personnel

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Commission is amending its regulation "Access Authorization for Licensee Personnel" to comply with a Commission policy easing security forms requirements for those individuals already possessing a security clearance granted by another Federal agency.

EFFECTIVE DATE: October 30, 1980.

FOR FURTHER INFORMATION CONTACT: Duane G. Kidd, Chief, Security Policy Branch, Division of Security, Office of Administration, United States Nuclear Regulatory Commission, Washington, D.C. 20555 (301) 427–4415.

SUPPLEMENTARY INFORMATION: 10 CFR Part 25, "Access Authorization for Licensee Personnel," was published in the **Federal Register** on March 5, 1980 (45 FR 14476) with an effective date of May 19, 1980. The effective date was changed to October 1, 1980 in a Federal Register Notice dated July 3, 1980 (45 FR 45256) to provide the Nuclear Regulatory Commission (NRC) additional time to furnish necessary administration guidance and for licensees to be able to achieve compliance with the regulations. The existing provisions of § 25.17 require that a complete set of NRC personnel security forms be completed as part of an application for a security clearance with NRC. This requirement was based on existing procedures and the necessity for the NRC Division of Security to review these forms and then seek copies of existing reports of investigations or initiate requests for new investigations. Realizing that many individuals already possess a security clearance or access authorization granted by another Federal agency and realizing that these security clearances were based on the same or very similar criteria and procedures, NRC sought to eliminate or substantially reduce the burden on licensees and their employees in obtaining an NRC security clearance. In this regard, the Commission, on July 17, 1980, approved a policy change in NRC's personnel security program that permits the NRC Division of Security to accept the certification of an individual's existing security clearance granted by another Federal agency and also eliminates the requirement to review reports of investigations. Based on this decision, the NRC Division of Security will not require new investigations for those individuals who had or were in processing for another Federal security clearance on October 1, 1980. This action may expedite the security clearance processing of individuals affected by this Part and may reduce the cost to licensees since new investigations will not be initiated. Additionally, the NRC Division of Security has decided to waive the forms requirements of § 25.17 for those individuals who possessed or who were in processing for another Federal security clearance on October 1, 1980. These amendments to 10 CFR Part 25 modify § 25.17 to permit individuals and licensees affected by this Part to submit applications in accordance with these revised procedures. Applications received after October 1, 1980 will be processed in accordance with the provisions of Part 25 and guidance supplied to licensees by the NRC Division of Security.

These revisions will substantially reduce the public burden by cutting the cost and reporting time required of licensees seeking NRC security clearances for their employees. These revisions will also reduce the burden on NRC by cutting the time and cost in processing applications for clearance. Furthermore, these revisions reflect public comments made during extensive discussions at public meetings held in Silver Spring, MD in April and May 1980. Therefore, the Commission for good cause finds that, in accordance with 5 U.S.C. 553(b) and (d), public comment procedures are not required, and these revisions become effective October 30, 1980.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and §§ 552 and 553 of Title 5 of the United States Code, the following amendments to 10 CFR Part 25 are published as a document subject to codification:

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46 FR 58281
Published 12/1/81
Effective 12/1/81

Licensing Requirements for the Storage of Spent Fuel In an Independent Spent Fuel Storage Installation; Minor Clarifying and Conforming Amendments

See Part 72 Statements of Consideration

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47 FR 9194
Published 3/4/82
Effective 4/5/82

10 CFR Parts 25 and 95

Requirements for Access to and Protection of National Security Information and Restricted Data; Minor Amendments

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to make needed clarifications and minor revisions in previously published requirements governing access to and control over National Security Information and/or Restricted Data. The amendments clarify the requirement that each NRC employee must have an access authorization before being allowed access to classified information, clarify certain requirements related to completing NRC forms and permit NRC to grant security facility approval prior to an initial security survey. The fee for licensee and license related "Q" access authorizations is also being updated due to increases in the Office of Personnel Management charges to NRC for full field security background investigations necessary for "Q" access authorization processing.

EFFECTIVE DATE: These amendments will be effective on April 5, 1982.

FOR FURTHER INFORMATION CONTACT: Duane G. Kidd, Chief, Security Policy Branch, Division of Security, Office of Administration, United States Nuclear Regulatory Commission, Washington, DC 20555 (301) 427–4415.

SUPPLEMENTARY INFORMATION: 10 CFR Parts 25 and 95 were originally published as final rules in the Federal Register on March 5, 1980 (45 FR 14476) and became effective October 1, 1980. The Commission now recognizes that the following changes and amendments as well as the annual revision to the access authorization fee schedule are needed for the reasons set out below.

The existing § 25.15 indicates that all NRC employees possess either an NRC "Q" or "L" access authorization and coupled with the "need-to-know" permits them access to National Security Information and/or Restricted Data. This change to § 25.15(c) notifies those affected by the rule that some individuals do, in fact, begin their NRC employment without an access authorization. These employees should not be permitted access to any classified information until their access authorization processing has been successfully completed.

Section 25.17(b) specifically identifies certain information which is required on NRC Form 237, "Request for Access Authorization." Reference to this specific data is being deleted since the necessary information is already requested on the form and in the instructions for completing the form. The reference to NRC Form 254A in § 25.17(c)(6) is being deleted since the form is no longer applicable to licensees and others affected by this rule. In order to conform to the style and format of other parts, the position and numbers of §§ 25.35 and 25.37 are being reversed.

Section 25.17 currently indicates that access authorization fees will be published in December of each year and will be applicable to each access authorization request received during the following calendar year. The initial fee schedule for this Part was published in the Federal Register on July 3, 1980 (45 FR 45256) and was updated by a Federal Register Notice dated January 27, 1981 (45 FR 8436). These fees are charged for access authorizations processed and services rendered by the NRC at the request of an identifiable recipient of the service, and are authorized under Title V of the Independent Offices Appropriation Act of 1952 (65 Stat. 290; 31 U.S.C. 483a). The only revision to the fee schedule is the increased cost for the processing of an NRC "Q" access authorization which involves a full field background investigation conducted by the Office of Personnel Management (OPM). The charge to NRC by OPM for this investigation was raised July 1, 1981 from $1200.00 to $1350.00. The new fee, applicable immediately, recovers this cost plus a part of the NRC's overhead associated with the processing of these access authorizations. The fees for an NRC "L" access authorization have not been changed.

Section 95.17 currently permits NRC to grant security facility approval to licensees or others covered by this Part following receipt of an acceptable security facility request, but only after NRC has conducted an on-site initial security survey. Some licensees initially covered by this part have already been approved as a security facility by other Federal departments or agencies whose facility security programs contain similar, and in some cases nearly identical, security requirements to those of NRC. NRC may determine that granting an interim security facility approval prior to an initial NRC security survey would be consistent with the national security. This change to § 95.17 permits such a determination with a security survey to be performed as soon thereafter as practical. The security survey may result in the granting of a security facility approval or a continuation or withdrawal of the interim security facility approval.

Section 95.25(g)(1) currently specifies that the names, addresses and telephone numbers of the security container custodian and all alternates having knowledge of the container's combination be posted on the outside of the container. This revision to § 95.25 will permit this information, in accordance with NRC security procedures, to be posted inside the container.

None of the changes, except for the update in the fee schedule, will increase public burden in meeting the requirements of these regulations. The changes are of a clarifying and updating nature. When the original Part 25 fee schedule was developed, it was recognized that the actual amount charged to NRC by OPM for conducting investigations would be the decisive factor governing future fees charged by NRC. This relationship between the amounts charged by OPM and the resulting fees charged by NRC still exists and was affected by the increase by OPM. Since the public had the opportunity to comment on this aspect of Part 25 as a proposed rule, it is not felt that any further benefits would be accrued by additional public comment at this time. Under these circumstances, NRC, for good cause, finds that notice of proposed rulemaking and public procedure thereon are unnecessary.

For good cause, the Commission has decided to make Appendix A to Part 25, "Fees for NRC Access Authorization," effective immediately. Appendix A sets forth the revised fee schedule for calendar year 1982. Section 25.17(e) states that access authorization fees will be published in December of each year and are applicable during the following calendar year. An immediate effective date will fulfill this requirement and avoid any delay in implementing the revised fee schedule.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, the Independent Offices Appropriation Act of 1952 and Section 553 of Title 5 of the United States Code, the following amendments to Parts 25 and 95 of Title 10, Chapter 1, Code of Federal Regulations are published as a document subject to codification.

47 FR 38675
Published 9/2/82
Effective 10/2/82

Revision and Clarification of Criteria and Procedures for Determining Eligibility for Access to Restricted Data or National Security Information or an Employment Clearance and Conforming Amendments

See Part 10 Statements of Consideration

48 FR 24318
Published 6/1/83
Effective 6/27/83

10 CFR Parts 25 and 95

Access to and Protection of National Security Information and Restricted Data

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to modify the requirements for submitting reports on classification/declassification actions, adding a specific marking to classified documents released to International Atomic Energy Agency (IAEA) representatives, maintaining records concerning visits involving classified information, and updating the regulations in accordance with the requirements of Executive Order 12356 and its Implementing Directive. These amendments provide additional guidance for handling classified drafts of documents and working papers and for obtaining approvals for the security of telecommunication and automatic data processing systems where classified information is involved. These amendments are necessary to incorporate experience gained under the current regulations and to prevent the unauthorized disclosure of National Security Information and Restricted Data.

EFFECTIVE DATE: June 27, 1983.

FOR FURTHER INFORMATION CONTACT: Richard A. Dopp, Security Policy Branch, Division of Security, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Telephone: (301) 427-4415.

SUPPLEMENTARY INFORMATION: On December 30, 1982 the Commission published proposed amendments in the **Federal Register** (47 FR 58275) to improve the clarity of direction of 10 CFR Parts 25 and 95 and to bring these parts into conformance with E.O. 12356 which was published in the **Federal Register** on April 6, 1982 (47 FR 14874).

A thirty day public comment period for the proposed rule expired January 31 1983. No public comments were received. The proposed amendments have been modified in response to editorial and minor content changes recommended by the NRC staff, and are being published in final form, to be effective thirty days after publication.

Effective August 1, 1982, E.O. 12356, together with an accompanying Information Security Oversight Office (ISOO) Implementing Directive, changed certain requirements governing the classification, declassification, downgrading and safeguarding of National Security Information. As explained more fully in connection with the specific changes indicated herein, Parts 25 and 95 required amendment to bring them into conformance with the provisions of E.O. 12356. Additional guidance and clarifying changes have been provided.

In particular, this rule revises the authority citations in 10 CFR Parts 25 and 95 and revises some definitions contained in these parts. The rule also clarifies the requirements for submittal of a complete security forms packet and makes other minor amendments.

Section 6.1 of E.O. 12356 reflects a change in the definition of the term "National Security Information." Sections 25.5 and 95.5 have been amended to reflect this revised definition. Additionally, § 95.5 has been revised to reflect changes in the definitions of "National Security," and "Classified Matter."

Section 25.17(c) in its original final form (45 FR 14476) required a full personnel security packet of forms identified in (1) through (6) of paragraph (c) to be submitted with each access authorization request. On October 30, 1980 (45 FR 71763), NRC amended § 25.17(c) and waived the full set of forms requirement for those individuals who already possessed an active security clearance from another Federal agency or who were being processed for a security clearance by another Federal agency on the effective date of the rule. The October 30, 1980 amendment substantially reduced the initial administrative burden on affected licensees who used the new procedure to obtain authorizations for affected employees. However, this provision continues to permit a reduced requirement for forms, even if the previously granted security clearance has since been terminated. This was not the staff's intent. The changes contained in this revision will continue to permit the certification of existing active Federal government access authorizations (with the reduced forms requirement) when based on adequate investigations which are not more than five years old.

Paragraph (c) of § 25.33, "Termination of access authorizations," currently requires the licensee or other organization official conducting a termination briefing to notify NRC in writing that a briefing was conducted and to forward the Security Termination Statement. Section 25.33(c) has been revised to reflect that the NRC Division of Security accepts the submission of the completed termination statement as evidence that the termination briefing has been conducted.

When Part 25 was originally published, NRC prescribed a number of recordkeeping requirements based on disposition schedules then in use. A recordkeeping requirement for documents relating to classified visits was not identified at that time. A records maintenance requirement for NRC Form 277 will provide the opportunity for NRC review of the classified visit program at the affected facility and provides assurance that only properly authorized individuals obtain access to classified matter during visits to other facilities and agencies. A revision of § 25.35 imposes this necessary recordkeeping requirement.

Sections 25.37 and 95.61, "Violations," have been revised to provide clear and concise notice of potential criminal liabilities and the availability of criminal penalties for the willful violation of the parts and to reflect the replacement of E.O. 12065 with E.O. 12356.

In order to permit licensees and others to make changes to their facility security plans, a new § 95.15(d) has been added. Changes which do not decrease the effectiveness of the plan may be made without prior NRC approval, but they must be submitted within two months after the changes have been made.

Classified documents which have been released to IAEA representatives will be identified by a special marking applied to them in accordance with instructions contained in the specific disclosure authorization letter provided by the NRC to the licensees. This additional means of identification and control for classified documents has been incorporated in § 95.36.

The requirements of E.O. 12356 modified the markings to be applied to classified documents. These modifications are reflected in the revisions made to § 95.37(c), "Markings required on face of classified document." Under E.O. 12356, the declassification of documents can occur on a specific date, event, or upon the originating agency's determination that the document may be declassified. Since the new E.O. eliminated the scheduled or routine review for declassification, § 95.37(c) has been revised to reflect this change. Additionally, § 95.37(c)(6), which addresses the extension of classification beyond six years, has been deleted since National Security Information documents under the new E.O. are no longer automatically declassified after that period.

The requirements of E.O. 12356 also modified the markings applied to transmittal documents. These new markings are set forth in the proposed revisions to § 95.37(h).

Section 95.37, "Classification and preparation of documents," provides detailed requirements for the marking and handling of classified documents. Experience in working with this section has demonstrated a need to provide more direction for the marking and handling of newly created documents. For this reason, a new § 95.37(k) has been added that provides specific direction for the marking and handling of drafts and working papers.

The existing § 95.39(d), "Telecommunication of classified information," and § 95.49, "Security of automatic data processing (ADP) systems," also demonstrated the need for revision to provide the necessary direction and requirements to establish a secure telecommunication or ADP system. Revised §§ 95.39(d) and 95.49 impose no additional requirements, but do offer more detailed direction.

Section 95.57 presently requires the submission of an NRC Form 790 whenever a document containing National Security Information or Restricted Data is generated or its classification is changed. The amendment to this section clarifies who should submit this report, what actions should be reported, and on what schedule.

Section 95.59, "Inspections," is being revised to reflect the replacement of E.O. 12065 with E.O. 12356.

Part 95, Appendix A, "Classification Guide for Safeguards Information," is being updatd to comply with E.O. 12356. A significant change occurs in the area of declassification guidance. Whereas previously, reviews at the end of seven or 20 years required, a determination by the originating agency is now required before information may be declassified.

Paperwork Reduction Act Statement

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget approval numbers 3150-0046, 0047, 0048

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission hereby certifies that this rule will not have a significant economic impact on any small entities. Each NRC licensee or other organization which may require access to National Security Information and/or Restricted Data used, processed, stored, reproduced, transmitted and destroyed in connection with a license or application for a license could potentially be impacted by this rule and required to provide adequate protection for National Security Information and/or Restricted Data. Only 12 entities (including five fuel cycle facilities, three transportation companies, one reactor and three other organizations) are currently required to meet the requirements of 10 CFR Parts 25 and 95. Since none of these have been determined to be small as defined by the Regulatory Flexibility Act of 1980 the Commission finds that this rule will not have a significant economic impact upon a substantial number of small entities.

List of Subjects

10 CFR Part 25

Classified information, Penalty, Reporting and recordkeeping requirements, Security measures.

10 CFR Part 95

Classified information, Penalty, Security measures.

Under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552 and 553, the following amendments to 10 CFR Parts 25 and 95 are published as a document subject to codification.

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48 FR 27533
Published 6/16/83
Effective 6/16/83

10 CFR Part 25

Amendment to the Timetable for the Publication of a Revised Access Authorization Fee Schedule

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to change the date of publication for the annual access authorization fee schedule from December to July. The Office of Personnel Management (OPM) sets the basic cost for the access authorization background investigations and notifies the NRC of adjustments for the cost on or about July 1. The change in publication date for the fee schedule will enable NRC to comply more promptly with OPM's revised cost adjustments.

EFFECTIVE DATE: June 16, 1983.

FOR FURTHER INFORMATION CONTACT: Richard A. Dopp, Chief, Security Policy Branch, Division of Security, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 Telephone: (301) 427-4549.

SUPPLEMENTARY INFORMATION: The current § 25.17 indicates that access authorization fees will be published in December of each year and will be applicable to each access authorization request received during the following calendar year. The Office of Personnel Management (OPM) conducts the access authorization background investigation for the NRC under an interagency agreement and set the basic cost for such investigations. However, OPM notifies the NRC of adjustments to the cost of these investigations on or about July 1 of each year. In order to comply more promptly with the OPM cost adjustment timetable, the NRC is amending this section to establish July rather than December as the month when the annual revised access authorization fee schedule will be published. In order to implement this change, no revised fee schedule was published during December 1982, and the next revised fee schedule will be published in July 1983. Since this is a minor procedural amendment, the notice and comment procedures of the Administrative Procedure Act (5 U.S.C. 553) do not apply, and good cause exists for making the amendment effective upon publication in the Federal Register.

Paperwork Reduction Act Statement

This final rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). Existing requirements were approved by the Office of Management and Budget approval number 3150–0046.

List Of Subjects in 10 CFR Part 25

Classified information, Penalty, Reporting and recordkeeping requirements, Security measures.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, the Independent Offices Appropriation Act of 1952 and Section 553 of Title 5 of the United States Code, the following amendment to Part 25 of Title 10, Chapter 1, Code of Federal Regulations is published as a document subject to codification.

48 FR 35069
Published 8/3/83
Effective 8/3/83

10 CFR Part 25

Revised Access Authorization Fees for Licensee Personnel

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to revise the access authorization investigation fees charged to licensee personnel who require access to National Security Information and/or Restricted Data. The revised fees will reflect the current access authorization investigation cost charged to the NRC by the Office of Personnel Management plus part of NRC's overhead associated with the processing of access authorization requests.

EFFECTIVE DATE: August 3, 1983.

FOR FURTHER INFORMATION CONTACT: Richard A. Dopp, Chief, Security Policy Branch, Division of Security, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone (301) 427–4549.

SUPPLEMENTARY INFORMATION: The Office of Personnel Management (OPM) conducts access authorization background investigations for the NRC under an interagency agreement and sets the basic cost for these investigations. In order to comply more promptly with the OPM cost adjustment timetable, § 25.17 was recently revised on June 16, 1983 (48 FR 27533) to establish July rather than December as the month when the annual access authorization fee schedule would be published. Since the access authorization fee schedule for this Part was last published in the Federal Register on March 4, 1982 (47 FR 9194), OPM has notified the NRC of an increase to the basic cost of the full field investigation. This OPM-conducted full field investigation is used by the NRC as a basis in granting a "Q" access authorization. Effective July 1, 1982, the full field investigation charge to NRC by OPM was raised from $1,350.00 to $1,450.00. Due to various cost efficiencies implemented by OPM, their July 1, 1983 full field investigation charge to the NRC has remained at $1,450.00. However, NRC has yet to reflect in its fee schedule the July 1, 1982 full field investigation cost increase by OPM. Therefore, the new fee, applicable immediately, recovers this $1,450.00 OPM-cost plus a part of NRC's overhead associated with the processing of these "Q" access authorizations. The NRC overhead cost equals approximately 15% of the OPM investigative cost, resulting in a revised NRC "Q" access authorization fee of $1,665.00. The collection of such fees is authorized by 31 U.S.C. 9701. The fees associated with the processing of an "L" access authorization have not been changed.

When the original Part 25 fee schedule was developed, it was recognized that the actual amount charged to NRC by OPM for conducting investigations would be the decisive factor governing future fees charged by NRC. This relationship between the amounts charged by OPM and the resulting fees charged by NRC continues and, therefore, has been affected by the July 1, 1982 increase by OPM. Since NRC is authorized to recover the costs incurred in processing access authorization requests pursuant to this Part, the NRC's amendatory action in this notice is merely ministerial and does not require the notice and comment procedures of the Administrative Procedure Act of 1980 (5 U.S.C. 553).

Paperwork Reduction Act Statement

This final rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). Existing requirements were approved by the Office of Management and Budget Approval Number 3150–0046.

List of Subjects in 10 CFR Part 25

Classified information, Investigations, Penalty, Reporting requirements, Security measures.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, Section 9701 of Title 31 and Section 553 of Title 5 of the United States Code, the following amendment to Part 25 of Title 10, Chapter I, Code of Federal Regulations is published as a document subject to codification.

49 FR 19623
Published 5/9/84
Effective 5/9/84

Information Collection Requirements; Display of OMB Control Numbers

See Part 0 Statements of Consideration

≫**49 FR 32172**
Published 8/13/84
Effective 8/13/84

10 CFR Part 25

Revised Access Authorization Fees for Licensee Personnel

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to revise the access authorization fees charged to licensee personnel who require access to National Security Information and/or Restricted Data. The revised fees will reflect the current access authorization investigation cost charged to the NRC by the Office of Personnel Management plus part of NRC's overhead associated with the processing of access authorization requests.

EFFECTIVE DATE: August 13, 1984.

FOR FURTHER INFORMATION CONTACT: Richard A. Dopp, Chief, Policy and Operational Support Branch, Division of Security, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone (301) 427–4549.

SUPPLEMENTARY INFORMATION: The Office of Personnel Management (OPM) conducts access authorization background investigations for the NRC under an interagency agreement and sets the basic cost for these investigations. Since the access authorization fee schedule was last published in the Federal Register on August 3, 1983 (48 FR 35069), OPM has notified the NRC of a decrease to the basic cost of the full field investigation. This OPM-conducted full field investigation is used by the NRC as a basis in granting a "Q" access authorization. Effective February 19, 1984, the full field investigation charge to NRC by OPM was lowered from $1,450.00 to $1,375.00 and is due to various cost efficiencies implemented by OPM. Therefore, the new NRC fee, applicable immediately, recovers this $1,375.00 OPM-cost plus a part of NRC's overhead associated with the processing of these "Q" access authorizations. The NRC overhead cost equals approximately 15% of the OPM investigative cost resulting in a revised NRC "Q" access authorization fee of $1,580.00, which is $85.00 lower than the fees implemented last year. The collection of these fees is authorized by 31 U.S.C. 9701. The fees associated with the processing of an "L" access authorization are not changed.

When the original Part 25 fee schedule was developed, it was recognized that the actual amount charged to NRC by OPM for conducting investigations would be the decisive factor governing future fees charged by NRC. This relationship between the amounts charged by OPM and the resulting fees charged by NRC continues and, therefore, has been affected by the February 19, 1984 decrease by OPM. Because NRC is authorized to recover the costs incurred in processing access authorization requests pursuant to this Part, the NRC's amendatory action in this notice is merely ministerial.

This action is being taken in order to inform NRC licensees of the reduction in the access authorization fees charged to licensees and others. These amendments relate solely to minor matters of agency management and do not alter the rights or adversely affect the interests of licensees. Accordingly, the notice and comment procedures of the Administrative Procedure Act, 5 U.S.C. 553, are inapplicable and the amendments may be made effective on publication in the **Federal Register**.

Environmental Impact: Categorical Exclusion

The NRC has determined that this final regulation is the type of action described in categorical exclusion 10 CFR 51.22(c)(1). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this final regulation.

Paperwork Reduction Act Statement

This final rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). Existing requirements were approved by the Office of Management and Budget Approval Number 3150-0046.

List of Subjects in 10 CFR Part 25

Classified information, Investigations, Penalty, Reporting and recordkeeping requirements, Security measures.

Under the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, 31 U.S.C. 9701 and 5 U.S.C. 553 the following amendment to 10 CFR Part 25 is published as a document subject to codification.

PART 30

RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL★ ★

GENERAL PROVISIONS

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30.70 Schedule A—Exempt concentrations.
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Authority: Sections 81, 82, 161, 182, 183, 186, 68 Stat. 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2111, 2112, 2201, 2232, 2236, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

Section 30.7 also issued under Pub. L. 95–601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 30.34(b) also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 30.61 also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

For purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 30.3, 30.34(b) and (c), 30.41 (a) and (c) and 30.53 are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§ 30.36, 30.51, 30.52, 30.55 and 30.56(b) and (c) are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

48 FR 39036

§ 30.1 Purpose and Scope.

This part prescribes rules applicable to all persons in the United States governing domestic licensing of byproduct material under the Atomic Energy Act of 1954, as amended (68 Stat. 919), and under Title II of the Energy Reorganization Act of 1974 (88 Stat. 1242), and exemptions from the domestic licensing requirements permitted by section 81 of the Act.

43 FR 6915

§ 30.2 Resolution of conflict.

The requirements of this part are in addition to, and not in substitution for, other requirements of this chapter. In any conflict between the requirements in this part and a specific requirement in another part of the regulations in this chapter, the specific requirement governs.

30 FR 8185

§ 30.3 Activities requiring license.

Except for persons exempt as provided in this part and Part 150 of this chapter, no person shall manufacture, produce, transfer, receive, acquire, own, possess, or use, byproduct material except as authorized in a specific or general license issued pursuant to the regulations in this chapter.

43 FR 6915

§ 30.4 Definitions.

As used in this part and Parts 31-35 of this chapter:

(a) "Act" means the Atomic Energy Act of 1954, (68 Stat. 919)- including any amendments thereto;

36 FR 1466

(a-1) "Department" and "Department of Energy" means the Department of Energy established by the Department of Energy Organization Act (Pub. L. 95-91, 91 Stat. 565, 42 U.S.C. 7101 *et seq.*) to the extent that the Department, or its duly authorized representatives, exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to sections 104 (b), (c) and (d) of the Energy Reorganization Act of 1974 (Pub. L. 93-438, 88 Stat. 1233 at 1237, 42 U.S.C. 5814) and retransferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Pub. L. 95-91, 91 Stat. 565 at 577-578, 42 U.S.C 7151).

45 FR 14199

(b) Terms defined in section 11 of the Act shall have the same meaning when used in the regulations in this part and Parts 31-35 to the extent such terms are not specifically defined in this part;

43 FR 6915

(c) "Agreement State" means any state with which the Atomic Energy Commission or the Nuclear Regulatory Commission has entered into an effective agreement under subsection 274b. of the Act. "Non-Agreement State" means any other State;

(d) "Byproduct material" means any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material;

(e) "Commission" means the Nuclear Regulatory Commission and its duly authorized representatives;

(f) "Curie" means that amount of radioactive material which disintegrates at the rate of 37 billion atoms per second;

(g) "Government agency" means any executive department, commission, independent establishment, corporation, wholly or partly owned by the United States of America which is an instrumentality of the United States, or any board, bureau, division, service, office, officer, authority, administration, or other establishment in the executive branch of the Government;

(h) "Human use" means the internal or external administration of byproduct material, or the radiation therefrom, to human beings;

(i) "License" except where otherwise specified means a license for byproduct material issued pursuant to the regulations in this part and Parts 31-35 of this chapter;

(j)(1) "Microcurie" means that amount of radioactive material which disintegrates at the rate of 37 thousand atoms per second;

(2) "Millicurie" means that amount of radioactive material which disintegrates at the rate of 37 million atoms per second;

(k) "Person" means (1) any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, Government agency other than the Commission or the Department , except that the Department shall be considered a person within the meaning of the regulations in this part to the extent that its facilities and activities are subject to the licensing and related regulatory authority of the Commission pursuant to section 202 of the Energy Reorganization Act of 1974 (88 Stat. 1244),[5] any State or any political subdivision of or any political entity within a State, any foreign government or nation or any political subdivision of any such government or nation, or other entity; and (2) any legal successor, representative, agent, or agency of the foregoing;

(l) "Physician" means an individual licensed by a State or territory of the United States, the District of Columbia or the Commonwealth of Puerto Rico to dispense drugs in the practice of medicine;

(m) "Production facility" means production facility as defined in the regulations contained in Part 50 of this chapter;

(n) "Radiographer" means any individual who performs or who, in attendance at the site where the sealed source or sources are being used, personally supervises radiographic operations and who is responsible to the licensee for assuring compliance with the requirements of the Commission's regulations and the conditions of the license;

(o) "Radiographer's assistant" means any individual who, under the personal supervision of a radiographer, uses radiographic exposure devices, sealed sources or related handling tools, or radiation survey instruments in radiography;

(p) "Radiography" means the examination of the structure of materials by nondestructive methods, utilizing sealed sources of byproduct materials;

(q) "Research and development" means (1) theoretical analysis, exploration, or experimentation; or (2) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials and processes. "Research and development" as used in this part and Parts 31-35 does not include the internal or external administration of byproduct material, or the radiation therefrom, to human beings;

(r) "Sealed source" means any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material;

(s) "Source material" means source material as defined in the regulations contained in Part 40 of this chapter;

(t) "Special nuclear material" means special nuclear material as defined in the regulations contained in Part 70 of this chapter;

(u) "United States", when used in a geographical sense, includes Puerto Rico and all territories and possessions of the United States;

(v) "Utilization facility" means a utilization facility as defined in the regulations contained in Part 50 of this chapter;

(w) "Commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the natural environment of a site but does not include changes desirable for the temporary use of the land for public recreational uses, necessary borings to determine site characteristics or other preconstruction monitoring to establish background information related to the suitability of a site or to the protection of environmental values.

(x) "Irretrievable well-logging source" means any sealed source containing licensed material that is pulled off or not connected to the wireline that suspends the source in the well and for which all reasonable effort at recovery has been expended.

§ 30.5 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part and Parts 31-35 by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

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[5] The Department facilities and activities identified in section 202 are:

(1) Demonstration Liquid Metal Fast Breeder reactors when operated as part of the power generation facilities of an electric utility system, or when operated in any other manner for the purpose of demonstrating the suitability for commercial application of such a reactor.

(2) Other demonstration nuclear reactors, except those in existence on January 19, 1975, when operated as part of the power generation facilities of an electric utility system, or when operated in any other manner for the purpose of demonstrating the suitability for commercial application of such a reactor.

(3) Facilities used primarily for the receipt and storage of high-level radioactive wastes resulting from licensed activities.

(4) Retrievable Surface Storage Facilities and other facilities authorized for the express purpose of subsequent long-term storage of high-level radioactive waste generated by the Department, which are not used for, or are part of, research and development activities.

46 FR 16030

§ 30.6 Communications.

(a) Unless otherwise specified or covered under the regional licensing program as provided in paragraph (b) of this section, any communication or report concerning the regulations in Parts 30 through 35 of this chapter and any application filed under these regulations may be submitted to the Commission as follows:

(1) By mail addressed to: Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(2) By delivery in person to the Commission's offices to the Director, Office of Nuclear Material Safety and Safeguards at:

(i) 1717 H Street, N.W., Washington, D.C.; or

(ii) 7915 Eastern Avenue, Willste Building, Silver Spring, Maryland.

50 FR 14692

(b) The Commission has delegated to the five Regional Administrators licensing authority for selected parts of its decentralized licensing program for nuclear materials as described in paragraph (b)(1) of this section. Any communication, report, or application covered under this licensing program must be submitted as specified in paragraph (b)(2) of this section.

(1) The delegated licensing program includes authority to issue, renew, amend, cancel, modify, suspend, or revoke licenses for nuclear materials issued pursuant to 10 CFR Parts 30 through 35, 40, and 70 to all persons except the United States Air Force and Navy for academic, medical, and industrial uses, with the following exceptions:

(i) Activities in the fuel cycle and special nuclear material in quantities sufficient to constitute a critical mass in any room or area. This exception does not apply to license modifications relating to termination of special nuclear material licenses that authorize possession of larger quantities when the case is referred for action from NRC's Headquarters to the Regional Administrators.

(ii) Health and safety design review of sealed sources and devices, and approval, for licensing purposes, of sealed sources and devices.

(iii) Processing of source material for extraction of metallic compounds (including Zirconium, Hafnium, Tantalum, Titanium, Niobium, etc.).

(iv) Distribution of products containing radioactive material to persons exempt pursuant to 10 CFR 32.11 through 32.26.

(v) New uses or techniques for use of byproduct, source, or special nuclear material.

(2) *Submissions.* (i) *Region I.* With the exception of the United States Air Force and Navy, the regional licensing program involves all Federal facilities in the region and non-Federal licensees in **the following Region I non-Agreement States and the District of Columbia:**

Connecticut, Delaware, Maine, Massachusetts, New Jersey, Pennsylvania, and Vermont. All inquiries, communications, and applications for a new license or an amendment or renewal of an existing license specified in paragraph (b)(1) of this section must be sent to: U.S. Nuclear Regulatory Commission, Region I, Nuclear Material Section B, 631 Park Avenue, King of Prussia, Pennsylvania 19406.

(ii) *Region II.* With the exception of the United States Air Force and Navy, the regional licensing program involves all Federal facilities in the region and non-Federal licensees in the following Region II non-Agreement States and territories: Virginia, West Virginia, Puerto Rico, and the Virgin Islands. All inquiries, communications, and applications for a new license or an amendment or renewal of an existing license specified in paragraph (b)(1) of this section must be sent to U.S. Nuclear Regulatory Commission, Region II, Material Radiation Protection Section, 101 Marietta Street, NW, Suite 2900, Atlanta, Georgia 30323.

50 FR 14692

(iii) *Region III.* With the exception of the United States Air Force and Navy, the regional licensing program involves all Federal facilities in the region and non-Federal licensees in **the following Region III non-Agreement States: Illinois, Indiana, Iowa, Michigan, Minnesota, Missouri, Ohio, and Wisconsin. All inquiries, communications, and applications for a new license or an amendment or renewal of an existing license specified in paragraph (b)(1) of this section must be sent to: U.S. Nuclear Regulatory Commission, Region III, Material Licensing Section, 799 Roosevelt Road, Glen Ellyn, Illinois 60137.**

(iv) Region IV. With the exception of the United States Air Force and Navy, the regional licensing program involves all Federal facilities in the region and non-Federal licensees in **the following Region IV non-Agreement States: Montana, Oklahoma, South Dakota, and Wyoming. All inquiries, communications, and applications for a new license or an amendment or renewal of an existing license specified in paragraph (b)(1) of this section must be sent to: U.S. Nuclear Regulatory Commission, Region IV, Material Radiation Protection Section, 611 Ryan Plaza Drive, Suite 1000, Arlington, Texas 76011.**

(v) *Region V.* With the exception of the United States Air Force and Navy, the regional licensing program involves all Federal facilities in the region and non-Federal licensees in **the following Region V non-Agreement States and a territory: Alaska, Hawaii, and Guam. All inquiries, communications, and applications for a new license or an amendment or renewal of an existing license specified in paragraph (b)(1) of this section must be sent to: U.S. Nuclear Regulatory Commission, Region V, Material Radiation Protection Section, 1450 Maria Lane, Suite 210, Walnut Creek, California 94596.**

47 FR 30452

§ 30.7 Employee protection.

(a) Discrimination by a Commission licensee, an applicant for a Commission license, or a contractor or subcontractor of a Commission licensee or applicant against an employee for engaging in certain protected activities is prohibited. Discrimination includes discharge and other actions that relate to compensation, terms, conditions, and privileges of employment. The protected activities are established in section 210 of the Energy Reorganization Act of 1974, as amended, and in general are related to the administration or enforcement of a requirement imposed under the Atomic Energy Act or the Energy Reorganization Act.

(1) The protected activities include but are not limited to—

(i) Providing the Commission information about possible violations of requirements imposed under either of the above statutes;

(ii) Requesting the Commission to institute action against his or her employer for the administration or enforcement of these requirements; or

(iii) Testifying in any Commission proceeding.

(2) These activities are protected even if no formal proceeding is actually initiated as a result of the employee assistance or participation.

(3) This section has no application to any employee alleging discrimination prohibited by this section who, acting without direction from his or her employer (or the employer's agent), deliberately causes a violation of any requirement of the Energy Reorganization Act of 1974, as amended, or the Atomic Energy Act of 1954, as amended.

(b) Any employee who believes that he or she has been discharged or otherwise discriminated against by any person for engaging in the protected activities specified in paragraph (a)(1) of this section may seek a remedy for the discharge or discrimination through an administrative proceeding in the Department of Labor. The administrative proceeding must be initiated within 30 days after an alleged violation occurs by filing a complaint alleging the violation with the Department of Labor, Employment Standards Administration, Wage and Hour Division. The Department of Labor

may order reinstatement, back pay, and compensatory damages.

(c) A violation of paragraph (a) of this section by a Commission licensee, an applicant for a Commission license, or a contractor or subcontractor of a Commission licensee or applicant may be grounds for—

(1) Denial, revocation, or suspension of the license.

(2) Imposition of a civil penalty on the licensee or applicant.

(3) Other enforcement action.

(d) Actions taken by an employer, or others, which adversely affect an employee may be predicated upon nondiscriminatory grounds. The prohibition applies when the adverse action occurs because the employee has engaged in protected activities. An employee's engagement in protected activities does not automatically render him or her immune from discharge or discipline for legitimate reasons or from adverse action dictated by nonprohibited considerations.

(e) Each licensee and each applicant shall post Form NRC-3, "Notice to Employees," on its premises. Posting must be at locations sufficient to permit employees protected by this section to observe a copy on the way to or from their place of work. Premises must be posted not later than 30 days after an application is docketed and remain posted while the application is pending before the Commission, during the term of the license, and for 30 days following license termination.

Note.—Copies of Form NRC-3 may be obtained by writing to the the Regional Administrator of the appropriate U.S. Nuclear Regulatory Commission Regional Office listed in Appendix D, Part 20 of this chapter or the Director, Office of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(f) The general licenses provided in Parts 31 and 35 of this chapter are exempt from paragraph (e) of this section.

47 FR 30452

§ 30.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 (U.S.C. 3501 et seq). OMB has approved the information collection requirements contained in this part under control number 3150-0017.

(b) The approved information collection requirements contained in this part appear in §§ 30.15, 30.19, 30.20, 30.32, 30.34, 30.36, 30.37, 30.38, 30.51, 30.55, and 30.56.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In §§ 30.32, 30.37, and 30.38, Form NRC-313I is approved under control number 3150-0042.

(2) In §§ 30.32, 30.37, and 30.38, Form NRC-313T is approved under control number 3150-0081.

(3) In § 30.36, Form NRC-314 is approved under control number 3150-0028.

(4) In §§ 30.37 and 30.38, Form NRC-313M is approved under control number 3150-0041.

(5) In §§30.37 and 30.38, Form NRC-313R is approved under control number 3150-0023.

49 FR 19623

EXEMPTIONS

43 FR 6915

§ 30.11 Specific exemptions.

(a) The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this part and Parts 31 through 35 of this chapter as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

(b) [Deleted 45 FR 6552]

46 FR 13971

(c) The DOE is exempt from the requirements of this part to the extent that its activities are subject to the requirements of Part 60 of this chapter.

47 FR 57446

(d) Except as specifically provided in Part 61 of this chapter, any licensee is exempt from the requirements of this part to the extent that its activities are subject to the requirements of Part 61 of this chapter.

45 FR 14199

§ 30.12 Persons using byproduct material under certain Department of Energy and Nuclear Regulatory Commission contracts.

Except to the extent that Department facilities or activities of the types subject to licensing pursuant to section 202 of the Energy Reorganization Act of 1974 are involved, any prime contractor of the Department is exempt from the requirements for a license set forth in sections 81 and 82 of the Act and from the regulations in this part to the extent that such contractor, under his prime contract with the Department manufactures, produces, transfers, receives, acquires, owns, possesses, or uses byproduct material for: (a) The performance of work for the Department at a United States Government-owned or controlled site, including the transportation of by-product material to or from such site and the performance of contract services during temporary interruptions of such transportation; (b) research in, or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof; or (c) the use or operation of nuclear reactors or other nuclear devices in a United States Government-owned vehicle or vessel. In addition to the foregoing exemptions and subject to the requirement for licensing of Department facilities and activities pursuant to section 202 of the Energy Reorganization Act of 1974, any prime contractor or subcontractor of the Department or the Commission is exempt from the requirements for a license set forth in sections 81 and 82 of the Act and from the regulations in this part to the extent that such prime contractor or subcontractor manufacturers, produces, transfers, receives, acquires, owns, possesses, or uses byproduct material under his prime contract or subcontract when the Commission determines that the exemption of the prime contractor or subcontractor is authorized by law; and that, under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

43 FR 6915

§ 30.13 Carriers.

Common and contract carriers, freight forwarders, warehousemen, and the U.S. Postal Service are exempt from the regulations in this part and Parts 31 through 35 of this chapter and the requirements for a license set forth in section 81 of the Act to the extent that they transport or store byproduct material in the regular course of carriage for another or storage incident thereto.

§ 30.14 Exempt concentrations.

(a) Except as provided in paragraphs (c) and (d) of this section, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in this part and Parts 31 through 35 of this chapter to the extent that such person receives, possesses, uses, transfers, owns or acquires products or materials containing byproduct material in concentrations not in excess of those listed in § 30.70.

30 FR 8185

(b) This section shall not be deemed to authorize the import of byproduct material or products containing byproduct material.

43 FR 6915

(c) A manufacturer, processor, or producer of a product or material in an agreement State is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in this part and Parts 31, 32, 33, and 34 of this chapter to the extent that he transfers byproduct material contained in a product or material in concentrations not in excess of those specified in § 30.70 and introduced into the product or material by a licensee holding a specific license issued by an Agreement State, the Commission, or the Atomic Energy Commission expressly authorizing such introduction. This exemption does not apply to the transfer of byproduct material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

30 FR 8185

(d) No person may introduce byproduct material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under this section or equivalent regulations of an Agreement State, except in accordance with a license issued pursuant to § 32.11 of this chapter or the general license provided in § 150.20 of this chapter.

34 FR 19546

§ 30.15 Certain items containing byproduct material.

43 FR 6915

(a) Except for persons who apply byproduct material to, or persons who incorporate byproduct material into, the following products, or persons who initially transfer for sale or distribution the following products containing byproduct material, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in Parts 20 and 30 through 35 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires the following products:

(next page is 30-5)

32 FR 13920

(1) Timepieces or hands or dials containing not more than the following specified quantities of byproduct material and not exceeding the following specified levels of radiation:

(i) 25 millicuries of tritium per timepiece,

(ii) 5 millicuries of tritium per hand,

(iii) 15 millicuries of tritium per dial (bezels when used shall be considered as part of the dial),

(iv) 100 microcuries of promethium-147 per watch or 200 microcuries of promethium-147 per any other timepiece,

(v) 20 microcuries of promethium-147 per watch hand or 40 microcuries of promethium-147 per other timepiece hand,

(vi) 60 microcuries of promethium-147 per watch dial or 120 microcuries of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial),

(vii) The levels of radiation from hands and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:

(*a*) For wrist watches, 0.1 millirad per hour at 10 centimeters from any surface,

(*b*) For pocket watches, 0.1 millirad per hour at 1 centimeter from any surface,

(*c*) For any other timepiece, 0.2 millirad per hour at 10 centimeters from any surface.

31 FR 5315

(2) Lock illuminators containing not more than 15 millicuries of tritum or not more than 2 millicuries of promethium-147 installed in automobile locks. The levels of radiation from each lock illuminator containing promethium-147 will not exceed 1 millirad per hour at 1 centimeter from any surface when measured through 50 milligrams per square centimeter of absorber.

(3) Balances of precision containing not more than 1 millicurie of tritium per balance or not more than 0.5 millicurie of tritum per balance part.

(4) Automobile shift quadrants containing not more than 25 millicuries of tritium.

32 FR 785

(5) Marine compasses containing not more than 750 millicuries of tritium gas and other marine navigational instruments containing not more than 250 millicuries of tritium gas.

31 FR 5315

(6) Thermostat dials and pointers containing not more than 25 millicuries of tritium per thermostat.

(7) [Deleted 34 FR 6651.]

35 FR 8820

(8) Electron tubes: *Provided*, That each tube does not contain more than one of the following specified quantities of byproduct material:

(i) 150 millicuries of tritium per microwave receiver protector tube or 10 millicuries of tritium per any other electron tube;

34 FR 6651

(ii) 1 microcurie of cobalt-60;

(iii) 5 microcuries of nickel-63;

(iv) 30 microcuries of krypton-85;

(v) 5 microcuries of cesium-137;

(vi) 30 microcuries of promethium-147;

And provided further, That the levels of radiation from each electron tube containing byproduct material do not exceed 1 millirad per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber.[3]

46 FR 26471

(9) Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of byproduct material: *Provided*, That:

(i) Each source contains no more than one exempt quantity set forth in § 30.71, Schedule B, and

(ii) Each instrument contains no more than 10 exempt quantities. For purposes of this paragraph (a)(9), an instrument's source(s) may contain either one type or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in § 30.71, Schedule B, provided that the sum of such fractions shall not exceed unity.

46 FR 46875

(iii) For purposes of this paragraph (a)(9), 0.05 microcurie of americium-241 is considered an exempt quantity under § 30.71, Schedule B.

43 FR 2386

(10) Spark gap irradiators containing not more than 1 microcurie of cobalt-60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least 3 gallons per hour (11.4 liters per hour).

43 FR 6915

(b) Any person who desires to apply byproduct material to, or to incorporate byproduct material into, the products exempted in paragraph (a) of this section, or who desires to initially transfer for sale or distribution such products containing byproduct material, should apply for a specific license pursuant to § 32.14 of this chapter, which license states that the product may be distributed by the licensee to persons exempt from the regulations pursuant to paragraph (a) of this section.

§ 30.16 Resins containing scandium-46 and designed for sand-consolidation in oil wells.

Any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in Parts 20 and 30-35 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires synthetic plastic resins containing scandium-46 which are designed for sand-consolidation in oil wells, and which have been manufactured or initially transferred for sale or distribution, in accordance with a specific license issued pursuant to § 32.17 of this chapter or equivalent regulations of an Agreement State. The exemption in this section does not authorize the manufacture or initial transfer for sale or distribution of any resins containing scandium-46.

36 FR 16898

§ 30.18 Exempt quantities.

(a) Except as provided in paragraphs (c) and (d) of this section, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in Parts 30-34 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material in individual quantities each of which does not exceed the applicable quantity set forth in § 30.71, Schedule B.

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[3] For purposes of this subparagraph "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pickup tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents.

(b) Any person who possesses byproduct material received or acquired prior to September 25, 1971, under the general license then provided in § 31.4 of this chapter is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in Parts 30-34 of this chapter to the extent that such person possesses, uses, transfers, or owns such byproduct material.

(c) This section does not authorize for purposes of commercial distribution the production, packaging, repackaging, or transfer of byproduct material, or the incorporation of byproduct material into products intended for commercial distribution.

(d) No person may, for purposes of commercial distribution, transfer byproduct material in the individual quantities set forth in § 30.71 Schedule B, knowing or having reason to believe that such quantities of byproduct material will be transferred to persons exempt under this section or equivalent regulations of an Agreement State, except in accordance with a license issued under § 32.18 of this chapter, which license states that the byproduct material may be transferred by the licensee to persons exempt under this section or the equivalent regulations of an Agreement State.

§ 30.19 Self-luminous products containing tritium, krypton-85, or promethium-147.

(a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147, and except as provided in paragraph (c) of this section, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in Parts 20 and 30-35 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85, or promethium-147 in self-luminous products manufactured, processed, produced, or initially transferred in accordance with a specific license issued pursuant to § 32.22 of this chapter, which license authorizes the initial transfer of the product for use under this section.

(b) Any person who desires to manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, or to transfer such products for use pursuant to paragraph (a) of this section, should apply for a license pursuant to § 32.22 of this chapter, which license states that the product may be transferred by the licensee to persons exempt from the regulations pursuant to paragraph (a) of this section or equivalent regulations of an Agreement State.

(c) The exemption in paragraph (a) of this section does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

§ 30.20 Gas and aerosol detectors containing byproduct material.

(a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing byproduct material, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in Parts 20 and 30-35 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued pursuant to § 32.26 of this chapter, which license authorizes the initial transfer of the product for use under this section.

(b) Any person who desires to manufacture, process, or produce gas and aerosol detectors containing byproduct material, or to initially transfer such products for use pursuant to paragraph (a) of this section, should apply for a license pursuant to § 32.26 of this chapter, which license states that the product may be initially transferred by the licensee to persons exempt from the regulations pursuant to paragraph (a) of this section or equivalent regulations of an Agreement State.

LICENSES

§ 30.31 Types of licenses.

Licenses for byproduct material are of two types: General and specific. Specific licenses are issued to named persons upon applications filed pursuant to the regulations in this part and Parts 32-35. General licenses are effective without the filing of applications with the Commission or the issuance of licensing documents to particular persons.

§ 30.32 Application for specific licenses.

(a) A person may file an application in duplicate on NRC Form 313, "Application for Material License," in accordance with the instructions in § 30.6 of this chapter. Information contained in previous applications, statements or reports filed with the Commission or the Atomic Energy Commission may be incorporated by reference, provided that the reference is clear and specific.

(b) The Commission may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the Commission to determine whether the application should be granted or denied or whether a license should be modified or revoked.

(c) Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on his behalf.

(d) An application for license filed pursuant to the regulations in this part and Parts 32-35 will be considered also as an application for licenses authorizing other activities for which licenses are required by the Act, provided that the application specifies the additional activities for which licenses are requested and complies with regulations of the Commission as to applications for such licenses.

(e) Each application for a byproduct material license, other than a license exempted from Part 170 of this chapter, shall be accompanied by the fee prescribed in § 170.31 of this chapter. No fee will be required to accompany an application for renewal or amendment of a license, except as provided in § 170.31 of this chapter.

(f) An application for a license to receive and possess byproduct material for the conduct of any activity which the Commission has determined pursuant to Subpart A of Part 51 of this chapter will significantly affect the quality of the environment shall be filed at least 9 months prior to commencement of construction of the plant or facility in which the activity will be conducted and shall be accompanied by any Environmental Report required pursuant to Subpart A of Part 51 of this chapter.

§ 30.33 General requirements for issuance of specific licenses.

(a) An application for a specific license will be approved if:

(1) The application is for a purpose authorized by the Act;

(2) The applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property;

(3) The applicant is qualified by training and experience to use the material for the purpose requested in such manner as to protect health and minimize danger to life or property;

(4) The applicant satisfies any special requirements contained in Parts 32-35; and

(5) In the case of an application for a license to receive and possess byproduct material for the conduct of any activity which the Commission determines will significantly affect the quality of the environment, the Director of Nuclear Material Safety and Safeguards or his designee, before commencement of construction of the plant or facility in which the activity will be conducted, on the basis of information filed and evaluations made pursuant to Subpart A of Part 51 of this chapter, has concluded, after weighing the environmental, economic, technical, and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. Commencement of construction prior to such conclusion shall be grounds for denial of a license to receive and possess byproduct material in such plant or facility. As used in this paragraph the term "commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, necessary roads for site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

(b) Upon a determination that an application meets the requirements of the Act, and the regulations of the Commission, the Commission will issue a specific license authorizing the possession and use of byproduct material (Form NRC-374, "Byproduct Material License").

§ 30.34 Terms and conditions of licenses.

(a) Each license issued pursuant to the regulations in this part and the regulations in Parts 31-35 shall be subject to all the provisions of the Act, now or hereafter in effect, and to all valid rules, regulations and orders of the Commission.

(b) No license issued or granted pursuant to the regulations in this part and Parts 31-35, nor any right under a license shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Commission shall, after securing full information, find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing.

(c) Each person licensed by the Commission pursuant to the regulations in this part and Parts 31-35 shall confine his possession and use of the byproduct material to the locations and purposes authorized in the license. Except as otherwise provided in the license, a license issued pursuant to the regulations in this part and Parts 31-35 of this chapter shall carry with it the right to receive, acquire, own, and possess, byproduct material. Preparation for shipment and transport of byproduct material shall be in accordance with the provisions of Part 71 of this chapter.

(d) Each license issued pursuant to the regulations in this part and Parts 31-35 shall be deemed to contain the provisions set forth in section 183b.-d., inclusive, of the Act, whether or not these provisions are expressly set forth in the license.

(e) The Commission may incorporate, in any license issued pursuant to the regulations in this part and Parts 31-35, at the time of issuance, or thereafter by appropriate rule, regulation or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of byproduct material as it deems appropriate or necessary in order to:

(1) Promote the common defense and security;

(2) Protect health or to minimize danger to life or property;

(3) Protect restricted data;

(4) Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be necessary or appropriate to effectuate the purposes of the Act and regulations thereunder.

(f) [Reserved]

(g) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators shall test the generator eluates for molybdenum-99 breakthrough in accordance with § 35.14(b)(4) (i) thru (iv).

§ 30.35 [Deleted 40 FR 8774.]

§ 30.36 Expiration and termination of licenses.

(a) Except as provided in § 30.37(b) and paragraph (d)(3) of this section, each specific license expires at the end of the day, in the month and year stated in the license.

(b) Each licensee shall notify the Commission immediately, in writing under § 30.6, and request termination of the license when the licensee decides to terminate all activities involving materials authorized under the license. This notification and request for

termination of the license must include the reports and information specified in paragraphs (d)(1) (iv) and (v) of this section. The licensee is subject to the provisions of paragraphs (d) and (e) of this section, as applicable.

(c) No less than 30 days before the expiration date specified in a specific license, the licensee shall either—

(1) Submit an application for license renewal under § 30.37; or

(2) Notify the Commission, in writing under § 30.6, if the licensee decides not to renew the license.

(d)(1) If a licensee does not submit an application for license renewal under § 30.37, the licensee shall, on or before the expiration date specified in the license—

(i) Terminate use of byproduct material;

(ii) Remove radioactive contamination to the extent practicable;

(iii) Properly dispose of byproduct material;

(iv) Submit a completed form NRC-314; and

(v) Submit a radiation survey report to confirm the absence of radioactive materials or to establish the levels of residual radioactive contamination, unless the licensee demonstrates the absence of residual radioactive contamination in some other manner. The licensee shall, as appropriate—

(A) Report levels of radiation in units of microrads per hour of beta and gamma radiation at one centimeter and gamma radiation at one meter from surfaces and report levels of radioactivity in units of disintegrations per minute (or microcuries) per 100 square centimeters removable and fixed on surfaces, microcuries per milliliter in water, and picocuries per gram in contaminated solids such as soils or concrete; and

(B) Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

(2) If no residual radioactive contamination attributable to activities conducted under the license is detected, the licensee shall submit a certification that no detectable radioactive contamination was found. If the information submitted under this paragraph and paragraphs (d)(1) (iv) and (v) of this section is adequate, the Commission will notify the licensee in writing that the license is terminated.

(3)(i) If detectable levels of residual radioactive contamination attributable to activities conducted under the license are found, the license continues in effect beyond the expiration date, if necessary, with respect to possession of residual byproduct material present as contamination until the Commission notifies the licensee in writing that the license is terminated. During this time, the licensee is subject to the provisions of paragraph (e) of this section.

(ii) In addition to the information submitted under paragraphs (d)(1) (iv) and (v) of this section the licensee shall submit a plan for decontamination, if required, as regards residual radioactive contamination remaining at the time the license expires.

(e) Each licensee who possesses residual byproduct material under paragraph (d)(3) of this section, following the expiration date specified in the license shall—

(1) Limit actions involving byproduct material to those related to decontamination and other activities related to preparation for release for unrestricted use; and

(2) Continue to control entry to restricted areas until they are suitable for release for unrestricted use and the Commission notifies the licensee in writing that the license is terminated.

48 FR 32324

§ 30.37 Applications for renewal of licenses.

(a) Application for renewal of a specific license shall be filed on Form NRC-313 in accordance with § 30.32.

49 FR 19623

30 FR 8185

(b) In any case in which a licensee, not less than thirty (30) days prior to the expiration of his existing license, has filed an application in proper form for renewal or for a new license, such existing license shall not expire until the application has been finally determined by the Commission.

49 FR 19623

§ 30.38 Applications for amendment of licenses.

Applications for amendment of a license shall be filed on Form NRC-313 in accordance with § 30.32 and shall specify the respects in which the licensee desires its license to be amended and the grounds for the amendment.

43 FR 6915

§ 30.39 Commission action on applications to renew or amend.

In considering an application by a licensee to renew or amend his license the Commission will apply the applicable criteria set forth in § 30.33 and Parts 32-35 of this chapter.

38 FR 33968

§ 30.41 Transfer of byproduct material.

(a) No licensee shall transfer byproduct material except as authorized pursuant to this section.

(b) Except as otherwise provided in his license and subject to the provisions of paragraphs (c) and (d) of this section, any licensee may transfer byproduct material:

(1) To the Administration;

40 FR 8774

(2) To the agency in any Agreement State which regulates radioactive material pursuant to an agreement under section 274 of the Act;

38 FR 33968

(3) To any person exempt from the licensing requirements of the Act and regulations in this part, to the extent permitted under such exemption;

(4) To any person in an Agreement State, subject to the jurisdiction of that State, who has been exempted from the licensing requirements and regulations of that State, to the extent permitted under such exemption;

(5) To any person authorized to receive such byproduct material under terms of a specific license or a general license or their equivalents issued by the Atomic Energy Commission, the Commission, or an Agreement State; or

43 FR 6915

(6) To a person abroad pursuant to an export license issued under Part 110 of this chapter;

(7) As otherwise authorized by the Commission in writing.

38 FR 33968

(c) Before transferring byproduct material to a specific licensee of the Commission or an Agreement State or to a general licensee who is required to register with the Commission or with an Agreement State prior to receipt of the byproduct material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of byproduct material to be transferred.

(d) The following methods for the verification required by paragraph (c) of this section are acceptable:

(1) The transferor may have in his possession, and read, a current copy of the transferee's specific license or registration certificate;

(2) The transferor may have in his possession a written certification by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of byproduct material to be transferred, specifying the license or registration certificate number, issuing agency and expiration date;

(3) For emergency shipments the transferor may accept oral certification by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of byproduct material to be transferred, specifying the license or registration certificate number, issuing agency and expiration date: *Provided*, That the oral certification is confirmed in writing within 10 days;

(4) The transferor may obtain other sources of information compiled by a reporting service from official records of the Commission or the licensing agency of an Agreement State as to the identity of licensees and the scope and expiration dates of licenses and registration; or

(5) When none of the methods of verification described in paragraphs (d)(1) to (4) of this section are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the Commission or the licensing agency of an Agreement State that the transferee is licensed to receive the byproduct material.

46 FR 55085

RECORDS, INSPECTIONS, TESTS, AND REPORTS

§ 30.51 Records.

(a) Each person who receives byproduct material pursuant to a license issued pursuant to the regulations in this part and Parts 31-35 shall keep records showing the receipt, transfer, and disposal of such byproduct material.

(b) Records which are required by the regulations in this part and Parts 31-35 or by license condition shall be maintained for the period specified by the appropriate regulation or license condition. If a retention period is not otherwise specified by regulation or license condition, such records shall be maintained until the Commission authorizes their disposition.

43 FR 6915

(c)(1) Records of receipt of byproduct material which must be maintained pursuant to paragraph (a) of this section shall be maintained as long as the licensee retains possession of the byproduct material and for two years following transfer, or disposal of the byproduct material. (2) [Deleted 43 FR 6915.] (3) Records of transfer of byproduct material shall be maintained by the licensee who transferred the material for five years after such transfer. (4) Records of disposal of byproduct material shall be maintained in accordance with § 20.401 (c) of this chapter.

(d)(1) Records which must be maintained pursuant to this part and Parts 31-35 may be the original or a reproduced copy of microform if such reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified by Commission regulations.

(2) If there is a conflict between the Commission's regulations in this part and Parts 31-35, license condition, or other written Commission approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the regulations in this part and Parts 31-35 for such records shall apply unless the Commission, pursuant to § 30.11, has granted a specific exemption from the record retention requirements specified in the regulations in this part or Parts 31-35.

30 FR 8185

§ 30.52 Inspections.

(a) Each licensee shall afford to the Commission at all reasonable times opportunity to inspect byproduct material and the premises and facilities wherein byproduct material is used or stored.

(b) Each licensee shall make available to the Commission for inspection, upon reasonable notice, records kept by him pursuant to the regulations in this chapter.

43FR 6915

§ 30.53 Tests.

Each licensee shall perform, or permit the Commission to perform, such tests as the Commission deems appropriate or necessary for the administration of the regulations in this part and Parts 31 through 35 of this chapter, including tests of:

30 FR 8185

(a) Byproduct material;

(b) Facilities wherein byproduct material is utilized or stored;

(c) Radiation detection and monitoring instruments; and

(d) Other equipment and devices used in connection with the utilization or storage of byproduct material.

46 FR 55085

§ 30.55 Tritium reports.

(a) [Reserved]

49 FR 24705

(b) [reserved]

43 FR 6915

(c) Except as specified in paragraph (d) of this section, each licensee who is authorized to possess tritium shall report promptly to the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter by telephone and telegraph, mailgram, or facsimile any incident in which an attempt has been made or is believed to have been made to commit a theft or unlawful diversion of more than 10 curies of such material at any one time or more than 100 curies of such material in any one calendar year. The initial report shall be followed within a period of fifteen (15) days by a written report submitted to the appropriate NRC Regional Office which sets forth the details of the incident and its consequences. Copies of such written report shall be sent to the Director of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

37 FR 9207

Subsequent to the submission of the written report required by this paragraph, the licensee shall promptly inform the Office of Inspection and Enforcement by means of a written report of any substantive additional information, which becomes available to the licensee, concerning an attempted or apparent theft or unlawful diversion of tritium.

(d) The reports described in this section are not required for tritium possessed pursuant to a general license provided in Part 31 of this chapter or for tritium contained in spent fuel.

49 FR 24705

(e) [reserved]

48 FR 39036

§ 30.56 Well-logging operations using sealed sources.

(a) A licensee may perform well-logging operations with a sealed source only after the licensee executes a written agreement with the well owner or operator that, within thirty (30) days after a well-logging source has been classified as irretrievable, the following requirements will be implemented:

(1) Each irretrievable well-logging source must be immobilized and sealed in place with a cement plug.

(2) A whipstock or other deflection device must be set at some point in the well above the cement plug, unless the cement plug and source are not accessible to any subsequent drilling operations.

(3) A permanent identification plaque, constructed of long lasting material such as stainless steel, brass, bronze, or monel, must be mounted at the surface of the well, unless the mounting of the plaque is not practical. The plaque must contain:

(i) The word "CAUTION";

(ii) A radiation symbol (the color requirement need not be met);

(iii) The date the source was abandoned;

(iv) The name of the well owner or well operator;

48 FR 39036

(v) The well name and well identification number(s) or other designation;

(vi) An identification of the sealed source(s) by radionuclide and quantity of activity;

(vii) The depth of the source and depth to the top of the plug; and

(viii) An appropriate warning.

(b) When a well-logging source becomes irretrievable, the licensee shall:

(1) Notify the Regional Administrator of the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter of the circumstances of the loss by telephone; and

(2) Obtain approval to implement abandonment procedures.

(c) The licensee shall, within 30 days after a well-logging source has been classified as irretrievable, make a report in writing to the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter. The licensee shall send a copy of the report to each appropriate State agency that has authority over the particular well-drilling operation. The report must contain the following information:

(1) Date of occurrence.

(2) A description of the irretrievable well-logging source involved, including radionuclide, quantity, and chemical and physical form.

(3) Surface location and identification of well.

(4) Results of efforts to immobilize and seal the source in place.

(5) Depth of source.

(6) Depth of the top of the cement plug.

(7) Depth of the well.

(8) Any other information (e.g., warning statement) contained on the permanent identification plaque.

(9) Notifications made to State agencies.

(10) A brief description of the attempted recovery efforts.

(d) Any licensee or applicant for a license may apply to the Commission for approval of proposed procedures to abandon an irretrievable well-logging source in a manner not otherwise authorized in paragraph (a) of this section.

(next page is 30-9a)

ENFORCEMENT

43 FR 6915

§ 30.61 Modification and revocation of licenses.

(a) The terms and conditions of each license issued pursuant to the regulations in this part and Parts 31 through 35 of this chapter shall be subject to amendment, revision or modification by reason of amendments to the Act, or by reason of rules, regulations and orders issued in accordance with the terms of the Act.

30 FR 8185

(b) Any license may be revoked, suspended or modified, in whole or in part, for any material false statement in the application or any statement of fact required under section 182 of the Act, or because of conditions revealed by such application or statement of fact or any report, record or inspection or other means which would warrant the Commission to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and provisions of the Act or of any rule, regulation or order of the Commission.

(c) Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

40FR8774

§ 30.62 Right to cause the withholding or recall of byproduct material.

30 FR 8185

The Commission may cause the withholding or recall of byproduct material from any licensee who is not equipped to observe or fails to observe such safety standards to protect health as may be established by the Commission, or who uses such materials in violation of law or regulation of the Commission, or in a manner other than as disclosed in the application therefor or approved by the Commission.

40 FR 8774

§ 30.63 Violations.

An injunction or other court order may be obtained prohibiting any violation of any provision of the Atomic Energy Act of 1954, as amended, or Title II of the Energy Reorganization Act of 1974, or any regulation or order issued thereunder. A court order may be obtained for the payment of a civil penalty imposed pursuant to section 234 of the Act for violation of section 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Act, or section 206 of the Energy Reorganization Act of 1974, or any rule, regulation, or order issued thereunder, or any term, condition, or limitation of any license issued thereunder, or for any violation for which a license may be revoked under section 186 of the Act. Any person who willfully violates any provision of the Act or any regulation or order issued thereunder may be guilty of a crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law.

40 FR 8774

SCHEDULES

§ 30.70 Schedule A—Exempt concentrations.

Element (atomic number)	Isotope	Column I Gas concentration µCi/ml[1]	Column II Liquid and solid concentration µCi/ml[2]
Antimony (51)	Sb 122	-----	3×10^{-4}
	Sb 124	-----	2×10^{-4}
	Sb 125	-----	1×10^{-3}
Argon (18)	A 37	1×10^{-3}	-----
	A 41	4×10^{-7}	-----
Arsenic (33)	As 73	-----	5×10^{-3}
	As 74	-----	5×10^{-4}
	As 76	-----	2×10^{-4}
	As 77	-----	8×10^{-4}
Barium (56)	Ba 131	-----	2×10^{-3}
	Ba 140	-----	3×10^{-4}
Beryllium (4)	Be 7	-----	2×10^{-2}
Bismuth (83)	Bi 206	-----	4×10^{-4}
Bromine (35)	Br 82	4×10^{-7}	3×10^{-3}
Cadmium (48)	Cd 109	-----	2×10^{-3}
	Cd 115m	-----	3×10^{-4}
	Cd 115	-----	3×10^{-4}
Calcium (20)	Ca 45	-----	9×10^{-5}
	Ca 47	-----	5×10^{-4}
Carbon (6)	C 14	1×10^{-6}	8×10^{-3}
Cerium (58)	Ce 141	-----	9×10^{-4}
	Ce 143	-----	4×10^{-4}
	Ce 144	-----	1×10^{-4}
Cesium (55)	Cs 131	-----	2×10^{-2}
	Cs 134m	-----	6×10^{-2}
	Cs 134	-----	9×10^{-5}
Chlorine (17)	Cl 38	9×10^{-7}	4×10^{-3}
Chromium (24)	Cr 51	-----	2×10^{-2}
Cobalt (27)	Co 57	-----	5×10^{-3}
	Co 58	-----	1×10^{-3}
	Co 60	-----	5×10^{-4}
Copper (29)	Cu 64	-----	3×10^{-3}
Dysprosium (66)	Dy 165	-----	4×10^{-3}
	Dy 166	-----	4×10^{-4}
Erbium (68)	Er 169	-----	9×10^{-4}
	Er 171	-----	1×10^{-3}
Europium (63)	Eu 152 (T/2=9.2 Hrs)	-----	6×10^{-4}
	Eu 155	-----	2×10^{-3}
Fluorine (9)	F 18	2×10^{-6}	8×10^{-3}
Gadolinium (64)	Gd 153	-----	2×10^{-3}
	Gd 159	-----	8×10^{-4}
Gallium (31)	Ga 72	-----	4×10^{-4}
Germanium (32)	Ge 71	-----	2×10^{-2}
Gold (79)	Au 196	-----	2×10^{-3}
	Au 198	-----	5×10^{-4}
	Au 199	-----	2×10^{-3}
Hafnium (72)	Hf 181	-----	7×10^{-4}
Hydrogen (1)	H 3	5×10^{-6}	3×10^{-2}
Indium (49)	In 113m	-----	1×10^{-2}
	In 114m	-----	2×10^{-4}
Iodine (53)	I 126	3×10^{-9}	2×10^{-5}
	I 131	3×10^{-9}	2×10^{-5}
	I 132	8×10^{-8}	6×10^{-4}
	I 133	1×10^{-8}	7×10^{-5}
	I 134	2×10^{-7}	1×10^{-3}
Iridium (77)	Ir 190	-----	2×10^{-3}
	Ir 192	-----	4×10^{-4}
	Ir 194	-----	3×10^{-4}
Iron (26)	Fe 55	-----	8×10^{-3}
	Fe 59	-----	6×10^{-4}
Krypton (36)	Kr 85m	1×10^{-6}	-----
	Kr 85	3×10^{-6}	-----
Lanthanum (57)	La 140	-----	2×10^{-4}
Lead (82)	Pb 203	-----	4×10^{-3}
Lutetium (71)	Lu 177	-----	1×10^{-3}
Manganese (25)	Mn 52	-----	3×10^{-4}
	Mn 54	-----	1×10^{-3}
	Mn 56	-----	1×10^{-3}
Mercury (80)	Hg 197m	-----	2×10^{-3}
	Hg 197	-----	3×10^{-3}
	Hg 203	-----	2×10^{-4}
Molybdenum (42)	Mo 99	-----	2×10^{-3}
Neodymium (60)	Nd 147	-----	6×10^{-4}
	Nd 149	-----	3×10^{-3}
Nickel (28)	Ni 65	-----	1×10^{-3}
Niobium (Columbium) (41)	Nb 95	-----	1×10^{-3}
	Nb 97	-----	9×10^{-3}
Osmium (76)	Os 185	-----	7×10^{-4}
	Os 191m	-----	3×10^{-2}
	Os 191	-----	2×10^{-3}
	Os 193	-----	6×10^{-4}
Palladium (46)	Pd 103	-----	3×10^{-3}
	Pd 109	-----	9×10^{-4}
Phosphorus (15)	P 32	-----	2×10^{-4}
Platinum (78)	Pt 191	-----	1×10^{-3}
	Pt 193m	-----	1×10^{-2}
	Pt 197m	-----	1×10^{-2}
	Pt 197	-----	1×10^{-3}
Potassium (19)	K 42	-----	3×10^{-3}
Praseodymium (59)	Pr 142	-----	3×10^{-4}
	Pr 143	-----	5×10^{-4}
Promethium (61)	Pm 147	-----	2×10^{-3}
	Pm 149	-----	4×10^{-4}
Rhenium (75)	Re 183	-----	6×10^{-3}
	Re 186	-----	9×10^{-4}
	Re 188	-----	6×10^{-4}

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[1] Values are given only for those materials normally used as gases.

[2] µCi/gm for solids.

Element (atomic number)	Isotope	Column I Gas concentration μCi/ml[1]	Column II Liquid and solid concentration μCi/ml[2]
Rhodium (45)	Rh 103m	------	1×10^{-1}
	Rh 105	------	1×10^{-3}
Rubidium (37)	Rb 86	------	7×10^{-4}
Ruthenium (44)	Ru 97	------	4×10^{-3}
	Ru 103	------	8×10^{-4}
	Ru 105	------	1×10^{-3}
	Ru 106	------	1×10^{-4}
Samarium (62)	Sm 153	------	8×10^{-4}
Scandium (21)	Sc 46	------	4×10^{-4}
	Sc 47	------	9×10^{-4}
	Sc 48	------	3×10^{-4}
Selenium (34)	Se 75	------	3×10^{-3}
Silicon (14)	Si 31	------	9×10^{-3}
Silver (47)	Ag 105	------	1×10^{-3}
	Ag 110m	------	3×10^{-4}
	Ag 111	------	4×10^{-4}
Sodium (11)	Na 24	------	2×10^{-3}
Strontium (38)	Sr 85	------	1×10^{-3}
	Sr 89	------	1×10^{-4}
	Sr 91	------	7×10^{-4}
	Sr 92	------	7×10^{-4}
Sulfur (16)	S 35	9×10^{-8}	6×10^{-4}
Tantalum (73)	Ta 182	------	4×10^{-4}
Technetium (43)	Tc 96m	------	1×10^{-1}
	Tc 96	------	1×10^{-3}
Tellurium (52)	Te 125m	------	2×10^{-3}
	Te 127m	------	6×10^{-4}
	Te 127	------	3×10^{-3}
	Te 129m	------	3×10^{-4}
	Te 131m	------	6×10^{-4}
	Te 132	------	3×10^{-4}
Terbium (65)	Tb 160	------	4×10^{-4}
Thallium (81)	Tl 200	------	4×10^{-3}
	Tl 201	------	3×10^{-3}
	Tl 202	------	1×10^{-3}
	Tl 204	------	1×10^{-3}
Thulium (69)	Tm 170	------	5×10^{-4}
	Tm 171	------	5×10^{-3}
Tin (50)	Sn 113	------	9×10^{-4}
	Sn 125	------	2×10^{-4}
Tungsten (Wolfram) (74)	W 181	------	4×10^{-3}
	W 187	------	7×10^{-4}
Vanadium (23)	V 48	------	3×10^{-4}
Xenon (54)	Xe 131m	4×10^{-6}	------
	Xe 133	3×10^{-6}	------
	Xe 135	1×10^{-6}	------
Ytterbium (70)	Yb 175	------	1×10^{-3}
Yttrium (39)	Y 90	------	2×10^{-4}
	Y 91m	------	3×10^{-2}
	Y 91	------	3×10^{-4}
	Y 92	------	6×10^{-4}
	Y 93	------	3×10^{-4}
Zinc (30)	Zn 65	------	1×10^{-3}
	Zn 69m	------	7×10^{-4}
	Zn 69	------	2×10^{-2}
Zirconium (40)	Zr 95	------	6×10^{-4}
	Zr 97	------	2×10^{-4}
Beta and/or gamma emitting byproduct material not listed above with half-life less than 3 years.	----------	1×10^{-10}	1×10^{-6}

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NOTE 1: Many radioisotopes disintegrate into isotopes which are also radioactive. In expressing the concentrations in Schedule A, the activity stated is that of the parent isotope and takes into account the daughters.

NOTE 2: For purposes of § 30.14 where there is involved a combination of isotopes, the limit for the combination should be derived as follows:

Determine for each isotope in the product the ratio between the concentration present in the product and the exempt concentration established in Schedule A for the specific isotope when not in combination. The sum of such ratios may not exceed "1" (i.e., unity).

Example:

$$\frac{\text{Concentration of Isotope A in Product 1}}{\text{Exempt concentration of Isotope A}} + \frac{\text{Concentration of Isotope B in Product}}{\text{Exempt concentration of Isotope B}} \leqq 1$$

§ 30.71 Schedule B.

Byproduct material	*Microcuries*
Antimony 122 (Sb 122)	100
Antimony 124 (Sb 124)	10
Antimony 125 (Sb 125)	10
Arsenic 73 (As 73)	100
Arsenic 74 (As 74)	10
Arsenic 76 (As 76)	10
Arsenic 77 (As 77)	100
Barium 131 (Ba 131)	10
Barium 133 (Ba 133)	10
Barium 140 (Ba 140)	10
Bismuth 210 (Bi 210)	1
Bromine 82 (Br 82)	10
Cadmium 109 (Cd 109)	10
Cadmium 115m (Cd 115m)	10
Cadmium 115 (Cd 115)	100
Calcium 45 (Ca 45)	10
Calcium 47 (Ca 47)	10
Carbon 14 (C 14)	100
Cerium 141 (Ce 141)	100
Cerium 143 (Ce 143)	100
Cerium 144 (Ce 144)	1
Cesium 131 (Cs 131)	1,000

36 FR 16898

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[1] Values are given only for those materials normally used as gases.

[2] μCi/gm for solids.

Byproduct material	*Microcuries*
Cesium 134m (Cs 134m)	100
Cesium 134 (Cs 134)	1
Cesium 135 (Cs 135)	10
Cesium 136 (Cs 136)	10
Cesium 137 (Cs 137)	10
Chlorine 36 (Cl 36)	10
Chlorine 38 (Cl 38)	10
Chromium 51 (Cr 51)	1,000
Cobalt 58m (Co 58m)	10
Cobalt 58 (Co 58)	10
Cobalt 60 (Co 60)	1
Copper 64 (Cu 64)	100
Dysprosium 165 (Dy 165)	10
Dysprosium 166 (Dy 166)	100
Erbium 169 (Er 169)	100
Erbium 171 (Er 171)	100
Europium 152 9.2h (Eu 152 9.2h)	100
Europium 152 13 yr (Eu 152 13 yr)	1
Europium 154 (Eu 154)	1
Europium 155 (Eu 155)	10
Fluorine 18 (F 18)	1,000
Gadolinium 153 (Gd 153)	10
Gadolinium 159 (Gd 159)	100
Gallium 72 (Ga 72)	10
Germanium 71 (Ge 71)	100
Gold 198 (Au 198)	100
Gold 199 (Au 199)	100
Hafnium 181 (Hf 181)	10
Holmium 166 (Ho 166)	100
Hydrogen 3 (H 3)	1,000
Indium 113m (In 113m)	100
Indium 114m (In 114m)	10
Indium 115m (In 115m)	100
Indium 115 (In 115)	10
Iodine 125 (I 125)	1
Iodine 126 (I 126)	1
Iodine 129 (I 129)	0.1
Iodine 131 (I 131)	1
Iodine 132 (I 132)	10
Iodine 133 (I 133)	1
Iodine 134 (I 134)	10
Iodine 135 (I 135)	10
Iridium 192 (Ir 192)	10
Iridium 194 (Ir 194)	100
Iron 55 (Fe 55)	100
Iron 59 (Fe 59)	10
Krypton 85 (Kr 85)	100
Krypton 87 (Kr 87)	10
Lanthanum 140 (La 140)	10
Lutetium 177 (Lu 177)	100
Manganese 52 (Mn 52)	10
Manganese 54 (Mn 54)	10
Manganese 56 (Mn 56)	10
Mercury 197m (Hg 197m)	100
Mercury 197 (Hg 197)	100
Mercury 203 (Hg 203)	10
Molybdenum 99 (Mo 99)	100
Neodymium 147 (Nd 147)	100
Neodymium 149 (Nd 149)	100
Nickel 59 (Ni 59)	100
Nickel 63 (Ni 63)	10
Nickel 65 (Ni 65)	100
Niobium 93m (Nb 93m)	10
Niobium 95 (Nb 95)	10
Niobium 97 (Nb 97)	10
Osmium 185 (Os 185)	10
Osmium 191m (Os 191m)	100
Osmium 191 (Os 191)	100
Osmium 193 (Os 193)	100
Palladium 103 (Pd 103)	100
Palladium 109 (Pd 109)	100
Phosphorous 32 (P 32)	10
Platinum 191 (Pt 191)	100
Platinum 193m (Pt 193m)	100
Platinum 193 (Pt 193)	100
Platinum 197m (Pt 197m)	100
Platinum 197 (Pt 197)	100
Polonium 210 (Po 210)	0.1
Potassium 42 (K 42)	10
Praseodymium 142 (Pr 142)	100
Praseodymium 143 (Pr 143)	100
Promethium 147 (Pm 147)	10
Promethium 149 (Pm 149)	10
Rhenium 186 (Re 186)	100
Rhenium 188 (Re 188)	100
Rhodium 103m (Rh 103m)	100
Rhodium 105 (Rh 105)	100
Rubidium 86 (Rb 86)	10
Rubidium 87 (Rb 87)	10
Ruthenium 97 (Ru 97)	100
Ruthenium 103 (Ru 103)	10
Ruthenium 105 (Ru 105)	10
Ruthenium 106 (Ru 106)	1
Samarium 151 (Sm 151)	10
Samarium 153 (Sm 153)	100
Scandium 46 (Sc 46)	10
Scandium 47 (Sc 47)	100
Scandium 48 (Sc 48)	10
Selenium 75 (Sc 75)	10
Silicon 31 (Si 31)	100
Silver 105 (Ag 105)	10
Silver 110m (Ag 110m)	1
Silver 111 (Ag 111)	100
Sodium 24 (Na 24)	10
Strontium 85 (Sr 85)	10
Strontium 89 (Sr 89)	1
Strontium 90 (Sr 90)	0.1
Strontium 91 (Sr 91)	10
Strontium 92 (Sr 92)	10
Sulfur 35 (S 35)	100
Tantalum 182 (Ta 182)	10
Technetium 96 (Tc 96)	10
Technetium 97m (Tc 97m)	100
Technetium 97 (Tc 97)	100
Technetium 99m (Tc 99m)	100
Technetium 99 (Tc 99)	10
Tellurium 125m (Te 125m)	10
Tellurium 127m (Te 127m)	10
Tellurium 127 (Te 127)	100
Tellurium 129m (Te 129m)	10
Tellurium 129 (Te 129)	100
Tellurium 131m (Te 131m)	10
Tellurium 132 (Te 132)	10
Terbium 160 (Tb 160)	10
Thallium 200 (Tl 200)	100
Thallium 201 (Tl 201)	100
Thallium 202 (Tl 202)	100
Thallium 204 (Tl 204)	10
Thulium 170 (Tm 170)	10
Thulium 171 (Tm 171)	10
Tin 113 (Sn 113)	10
Tin 125 (Sn 125)	10
Tungsten 181 (W 181)	10
Tungsten 185 (W 185)	10
Tungsten 187 (W 187)	100
Vanadium 48 (V 48)	10
Xenon 131m (Xe 131m)	1,000
Xenon 133 (Xe 133)	100
Xenon 135 (Xe 135)	100
Ytterbium 175 (Yb 175)	100
Yttrium 90 (Y 90)	10
Yttrium 91 (Y 91)	10
Yttrium 92 (Y 92)	100
Yttrium 93 (Y 93)	100
Zinc 65 (Zn 65)	10
Zinc 69m (Zn 69m)	100
Zinc 69 (Zn 69)	1,000
Zirconium 93 (Zr 93)	10
Zirconium 95 (Zr 95)	10
Zirconium 97 (Zr 97)	10
Any byproduct material not listed above other than alpha emitting byproduct material	0.1

[Note removed 49 FR 19623]

PART 30

RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

PROPOSED RULE MAKING

45 FR 70874

Published 10/27/80

Comment period expires 12/11/80

10 CFR Parts 30, 32, 70, and 150

Exemption of Technetium-99 and Low-Enriched Uranium as Residual Contamination in Smelted Alloys

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission is considering amending its regulations to exempt from licensing and regulatory requirements technetium-99 and low-enriched uranium as residual contamination in any smelted alloy. The Commission is also proposing requirements for issuing specific licenses to persons desiring to smelt scrap or to initially transfer smelted alloys containing technetium-99 or low-enriched uranium as a residual contamination. The Commission is proposing these rule changes in response to a Department of Energy request to amend the Commission's present specific licensing requirements that have the effect of inhibiting trade in metal scrap contaminated with small amounts of these two radioactive materials.

DATES: Comment period expires December 11, 1980. Comments received after December 11, 1980 will be considered if it is practical to do do, but assurance of consideration cannot be given except as to comments filed on or before.

ADDRESSES: All interested persons who desire to submit written comments or suggestions for consideration in connection with the proposed amendments and draft environmental impact statement should send them to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 29555, Attention: Docketing and Service Branch. Copies of correspondence cited below and comments on the proposed amendments and draft environmental impact statement may be examined at the Commission's Public Document Room at 1717 H Street NW., Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Mr. J. J. Henry, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (301-443-5946).

SUPPLEMENTARY INFORMATION: Under current NRC regulations, no person may possess, use, or transfer technetium-99 or low-enriched uranium (defined in 10 CFR 70.51(a)(2) as that uranium whose isotope content is less than 20 percent uranium-235 by weight) as contaminants in metals except as authorized in a specific license issued by the NRC pursuant to 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," or 10 CFR Part 70, "Domestic Licensing of Special Nuclear Materials," as appropriate. The effect of the requirements for specific licenses has been to inhibit trade in metal scrap contaminated with small amounts of these two radioactive materials and prevent recycling by the secondary metals industry of smelted alloys containing these two radioactive materials as residual contamination.

Rulemaking Initiation

The Department of Energy has underway Cascade Improvement Programs and Cascade Upgrading Programs begun by the AEC at all three U.S. uranium enrichment plants—Oak Ridge, TN, Portsmouth, OH, and Paducah, KY. In the early 1970s, a market survey showed that no scrap dealers or processors would purchase any of the metal scrap generated by the programs if their customers would be required to hold specific licenses to possess or use recycled contaminated scrap.

Without relief from requirements for licenses, sizeable quantities of enrichment plant scrap—31,800 metric tons of iron and steel, 8,400 metric tons of nickel, and 1,600 metric tons of copper—would have to be treated as radioactive waste and buried by 1981 instead of being sold for tens of millions of dollars.

Based on these and other factors, the Director, Division of Waste Management and Transportation, AEC, by memorandum dated February 12, 1974, requested the assistance of the Director, Directorate of Regulatory Standards, AEC, in establishing a de minimis quantity for enriched uranium in scrap metal. The memorandum of response dated March 28, 1974, noted impending legislation to amend the Atomic Energy Act of 1954 to authorize AEC to exempt special nuclear material and suggested coordination so that language of any proposed exemption would be consistent with the legislation.

In the spring of 1974, L. Rogers, Director of Regulatory Standards, Atomic Energy Commission, presented a statement before the Joint Committee on Atomic Energy, U.S. Congress supporting an amendment of section 57 of the Atomic Energy Act of 1954 to give authority to exempt small quantities of special nuclear material to the former Atomic Energy Commission, the predecessor of the Nuclear Regulatory Commission. In his testimony, Mr. Rogers stated:

> . . . Equipment and materials in the nuclear industry are sometimes contaminated with levels of special nuclear material which cannot practically be removed but which are low enough that they do not constitute a radiation safety problem. An exemption from licensing of such special nuclear material would allow the reuse of recycling of the contaminated equipment and materials in an economic manner which would also conserve resources, rather than requiring the otherwise unnecessary controlled disposal of such contaminated equipment and materials as radioactive wastes.

After further consideration and data collection, the Energy Research and Development Administration (a successor of AEC) by letter dated September 8, 1976, transmitted to NRC an environmental impact assessment in which ERDA proposed: (1) An exemption of smelted metal contaminated with uranium enriched up to 20% uranium-235 providing the total uranium content in the metal does not exceed 17.5 parts per million; and (2) The addition of technetium-99 at a concentration of 8.6×10^{-2} microcuries/gram (equivalent to 5 parts per million) to Column II, Schedule A, 10 CFR 30.70, "Exempt Concentrations."

By letter dated July 9, 1979, the Department of Energy indicated the department's continued need or regulations to allow the sale of metal scrap contaminated with de minimis quantities of enriched uranium and technetium-99.

Proposed Action

The Commission is proposing to exempt from licensing and regulatory requirements any person who receives, possesses, uses, or transfers technetium-99 or low-enriched uranium as a residual contamination in any smelted alloys. The technetium-99 and low-enriched uranium would be minor constitutents less than 5 parts per million and 17.5 parts per million, respectively, of representative samples of smelted alloy products.

The proposed exemptions would not authorize the transfer of smelted alloy containing byproduct material other than technetium-99 as residual contamination, source material, other than low-enriched uranium as residendual contamination. In that event, the smelted alloy would also have to be exempt from the other applicable licensing and regulatory requirements of 10 CFR Parts 30–35, 40, and 70 to be transferred for use under the proposed exemptions.

Persons who smelt scrap contaminated with technetium-99 or low-enriched uranium or persons who initially transfer for sale or distribution smelted alloys containing technetium-99 or low-enriched uranium as residual contamination in the smelted alloys would not be exempt from requirements for specific licenses authorizing transfer to exempt persons. This means, among other things, that the slag produced by licensed smelters would be subject to specific licensing controls with regard to transfer of byproduct material (10 CFR 30.41) and special nuclear material (10 CFR 70.42). It is expected that slag from scrap generated at Department of Energy facilities would be returned to the Department of Energy for ultimate disposal. Slag from scrap generated at NRC licensed facilities would be disposed of in a safe manner, for example by transfer to commercial firms to the extent specific services and volumes are available for disposal of such low-level radioactive waste.

Basis for Technetium-99 Limit

The major source of technetium compounds and mixtures stems from the fission of uranium-235. Among the most important of the technetium isotopes is technetium-99, which exhibits a high fission yield from uranium-235 of 6.2 percent and a long half-life of 210,000 years. The nature of technetium is such that in the presence of hydrogen fluoride it forms volatile compounds and thereby becomes a trace contaminant of uranium hexafluoride.

Feed material specifications, published by the U.S. Department of Energy for uranium hexafluoride delivered to uranium enrichment plants, control the content of technetium-99 in the feed material by a specification on maximum beta particle radiation which allows a maximum beta activity of only 10 percent of the beta activity of aged natural uranium.

During the enrichment process, technetium deposits on all materials that come in contact with uranium hexafluoride. In the case of scrap metal generated in the Cascade Improvement Program and Cascade Upgrading Program, the combination of feed material specification, deposition rates, and mechnical and chemical decontamination results in scrap metal contaminated with a maximum of 5 parts per million technetium-99.

There is essentially no removal of technetium from metal during smelting processes. Therefore, the Commission is proposing for technetium-99 a concentration limit of 5 parts per million which is achievable by mechanical and chemical decontamination techniques prior to smelting scrap metal.

Basis for Uranium Limit

Because the proposed amendments of Part 70 involve special nuclear material, the Commission is proposing to base the uranium element concentration limit on the concentration of the uranium-235 isotope in the smelted alloys. By specifying that the uranium be low-enriched uranium (uranium whose isotope content is less than 20 percent uranium-235 by weight) at a maximum concentration of 17.5 parts per million uranium element in smelted alloys, the Commission is proposing to place a maximum concentration limit of 3.5 parts per million for uranium-235 in smelted alloys. This is consistent with the uranium-235 concentration in any alloy that is exempt under paragraph (a of 10 CFR 40.13, "Unimportant Quantities of Source Material." The alloy is exempt if it contains less than 0.05 percent by weight source material which includes uranium whose isotope content is 0.711 percent or less of uranium-235 by weight.

The Commission is proposing that the low-enriched uranium be residual contamination in smelted alloys. Based on this and the other factors set out above, the Commission considers the low-enriched uranium would be diluted in such a way that it would no longer be usable for any nuclear activity relevant from the point of view of safeguards and would be practicably irrecoverable.

Specific Licensing Conditions

The requirements for specific licenses to smelt scrap or to initially transfer smelted alloys containing technetium-99 or low-enriched uranium specify that the applicant must submit a description of decontamination and smelting procedures, sampling procedures, and analytical procedures.

The proposed amendments, in effect, will make the persons initially transferring smelted alloys responsible for assuring that such alloys meet the specifications set out in proposed 10 CFR 30.21 and/or 10 CFR 70.15. The specifically licensed person who smelts scrap or initially transfers smelted alloys must be able to certify to any interested person that the smelted alloy initially transferred has been smelted, sampled, and analyzed using procedures sufficient to provide reasonable assurance that the technetium-99 or low-enriched uranium is residual contamination in the smelted alloy in which the technetium-99 or low-enriched uranium are minor constituents less than 5 parts per million or 17.5 parts per million, respectively, of representative samples of billets, ingots, or other smelted alloy products. (The Department of Energy, and certain of its contractors, are exempt from licensing and could therefore make transfers to exempt persons without specific NRC authorization. The Commission relies upon the Department to establish internal control procedures that will assure that the contamination levels of smelted scrap which it transfers are within the limits set forth in these rules.)

The requirement for a specific license to smelt scrap is not intended to require a specific license to recycle any material from smelted alloys. Subsequent possession, use, transfer, and disposal of the technetium-99 and low-enriched uranium in resmelted alloys, the resulting slag, and new products by all other persons would be exempted from licensing and regulatory requirements of the Commission under 10 CFR Parts 30 and 70.

Benefits and Costs

The benefits of the proposed action come from the value added, costs saved, and energy saved by recycling contaminated metal scrap into salable smelted alloys.

If the total net benefits are expresed in dollars for building a smelter at Oak Ridge, TN, they would be (for enrichment plant scrap) $34.2 million from 8,400 metric tons of nickel, $2.3 million from 1,600 metric tons of copper, and $5.1 million from 31,800 metric tons of steel. Other alternatives (commercial smelter, Fernald, OH, smelter) yield similar total net dollar benefits.

The costs of the proposed action are primarily the radiological impacts from the smelting of scrap and the subsequent possession, use, and disposal of smelted alloys by exempt persons. The nonradiological impacts are similar for both contaminated and noncontaminated metal scrap.

If the radiological impacts are expressed in individual doses, collective doses, and health effects, they would be (for enrichment plant scrap):

Maximum Individual Total-Body Dose Rate (working 1000 hr/yr inside "vault")	0.01 rem/yr
Maximum Individual Total-Body Dose Commitment (daily ingestion of iron tonic over 1 year)	0.002 rem.
Maximum Individual Local Skin Dose (dose to wrist from bracelet worn 50 years)	15 rems
Maximum Individual Contact Bone Dose (dose from pin implanted 50 years)	20 rems.
Occupational (total scrap smelting)	0.01 person-rem.
General Population (total scrap)	80 person-rems.
Health Effects from Population Dose (incremental number of cancers in exposed population)	< 1

Proposed Findings

The Commission is considering a

finding that exemption from licensing requirements for the receipt, possession, use, or transfer of technetium-99 as residual contamination in any smelted alloy under the conditions set forth below will not constitute an unreasonable risk to the common defense and security and to the health and safety of the public.

The Commission is also considering a finding that exemption from licensing requirements for the receipt, possession, use, or transfer of low-enriched uranium as residual contamination in any smelted alloy under the conditions set forth below would not be inimical to the common defense and security and would not constitute an unreasonable risk to the health and safety of the public.

The provisions of § 150.15(a)(6) of 10 CFR Part 150, "Exemptions and Continued Regulatory Authority in Agreement States Under Section 274," would be amended to cover any equipment, device, commodity, or other product containing special nuclear material. Accordingly, the transfer of possession or control by persons in Agreement States who produce smelted alloys for use by exempt persons would be subject to the Commission's licensing and regulatory requirements, even though the scrap is smelted under an Agreement State license. Such producers wishing to transfer possession or control of smelted alloys for use by exempt persons would be required to obtain a specific license issued by the Commission.

Availability of Draft Environmental Statement

Pursuant to the National Environmental Policy Act of 1969, and the Commission's regulations in 10 CFR Part 51, "Licensing and Regulatory Policy and Procedures for Environmental Protection," the Commission's Office of Standards Development has prepared a draft environmental impact statement using the enrichment plant scrap as an example source for smelted alloys. (The decommissioning of uranium enrichment plants, nuclear power reactors, uranium hexafluoride plants, and fuel facilities would, under present regulations, all be major Federal actions requiring the preparation of environmental impact statements to evaluate, among other things, the environmental, economic, and radiological health impacts of smelting scrap and transferring smelted alloy.) The statement is available for inspection by the public in the Commission's Public Document Room at 1717 H Street NW., Washington, D.C. Single copies of the statement (NUREG-0518) may be obtained by request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Office of Standards Development.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and section 553 of title 5 of the United States Code, notice is hereby given that adoption of the following amendments to 10 CFR Parts 30, 32, 70, and 150 is contemplated.

PART 30—RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

1. In 10 CFR Part 30, a new § 30.21 is added to read as follows:

§ 30.21 Smelted alloys containing technetium-99 as residual contamination.

(a) Except as provided in paragraph (c) of this section, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in Parts 30–35 of this chapter to the extent that such person receives, possesses, uses, or transfers technetium–99 as residual contamination (1) in any smelted alloy in which the technetium–99 is a minor constituent less than 5 parts per million of a representative sample of the smelted alloy, or (2) in any material into which such smelted alloy or its constituents may have been converted.

(b) The exemption in paragraph (a) of this section does not authorize the transfer of smelted alloy containing:

(1) Byproduct material other than technetium–99 as residual contamination except in accordance with the requirements of this part and Parts 31–35 of this chapter; or

(2) Source material or special nuclear material except in accordance with the requirements of Parts 40 and 70 of this chapter.

(c) Any person who desires to smelt scrap contaminated with technetium-99 or who desires to initially transfer for sale or distribution smelted alloys containing technetium-99 as residual contamination in the smelted alloy to persons exempt under paragraph (a) of this section or equivalent regulations of an Agreement State, should apply for a specific license issued pursuant to § 32.30 of this chapter, which license states that the technetium-99 as residual contamination in the smelted alloy may be transferred by the licensee to persons exempt under paragraph (a) of this section or equivalent regulations of an Agreement State.

PART 32—SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

2. In 10 CFR Part 32, the authority statement immediately preceding § 32.1 is revised to read as follows

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, 42 U.S.C. 2111, 2201, 2232, 2233. For the purposes of sec. 223, 68 Stat. 958, as amended; 42 U.S.C. 2273, 32.12, 32.16, 32.20, 32.25(c), 32.29(c), 32.30(b), 32.52, 32.56, 32.60, 32.63 issued under sec. 161, 68 Stat. 950, as amended; 42 U.S.C. 2201(o), unless otherwise noted.

3. In 10 CFR Part 32, a new § 32.30 is added to read as follows:

§ 32.30 Smelted alloys containing technetium-99 as residual contamination: requirements for license to smelt scrap or to initially transfer.

(a) An application for a specific license to smelt scrap contaminated with technetium-99 or to initially transfer for sale or distribution smelted alloys containing technetium-99 as residual contamination for use pursuant to § 30.21 of this chapter or equivalent regulations of an Agreement State, will be approved if:

(1) The applicant satisfies the general requirements of § 30.33 of this chapter: *Provided, however,* That the requirements of § 30.33(a)(2) and (3) of this chapter do not apply to an application for a license to transfer technetium-99 in any alloy smelted pursuant to a license issued by an Agreement State; and

(2) The applicant submits a description of:

(i) Procedures for prior decontamination of the scrap and smelting of the scrap sufficient to provide reasonable assurance that the technetium-99 will be residual contamination in the resulting billets, ingots, or other smelted alloy products in which the technetium-99 is a minor constituent less than 5 parts per million of representative samples of the billets, ingots, or other smelted alloy products;

(ii) Sampling procedures sufficient to demonstrate that the material taken for analysis is a representative sample of the billet, ingot, or other smelted alloy product being analyzed; and

(iii) Analytical procedures to estimate technetium-99 concentrations with sufficient precision and accuracy to provide reasonable assurance that the technetium-99 is less than 5 parts per million of representative samples of the billets, ingots, or other smelted alloy products being analyzed.

(b) Each person licensed under paragraph (a) of this section shall file an annual report with the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, with a copy to the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter, which shall identify the type and quantity of smelted alloy produced during the reporting period and the concentrations of technetium-99 in the smelted alloy billets, ingots, or other products at the time of transfer of the technetium-99 by the licensee. If no transfers of technetium-99 have been made pursuant to paragraph (a) of this section during the reporting period, the report shall so indicate. The report shall cover the year ending June 30, and shall be filed within 30 days thereafter.

PART 70—DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

4. In 10 CFR Part 70, the authority statement immediately preceding the undesignated center heading GENERAL PROVISIONS is revised to read as follows:

Authority: Secs. 51, 53, 161, 182, 183, 68 Stat. 929, 930, as amended, 948, as amended, 953, as amended, 954 (42 U.S.C. 2071, 2073, 2201, 2232, 2233); secs. 202, 206, 88 Stat. 1244, 1246 (42 U.S.C. 5842, 5846) unless otherwise noted. For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273), 70.32(a)(6) and 70.41(a) issued under sec. 161b, 68 Stat 948; 42 U.S.C. 2201(b) and 70.38(b) and 70.51 to 70.55 issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)), unless otherwise noted

5. In 10 CFR Part 70, new §§ 70.15 and 70.38 are added to read as follows:

§ 70.15 Low-enriched uranium as residual contamination in smelted alloys.

(a) Except as provided in paragraph (c) of this section, any person is exempt from the requirements for a license set forth in section 53 of the Act and from the regulations in this part to the extent that such person receives, possesses, uses, or transfers low-enriched uranium as residual contamination (1) in any smelted alloy in which the uranium element is a minor constituent less than 17.5 parts per million of a representative sample of the smelted alloy, or (2) in any material into which such smelted alloy or its constituents may have been converted.

(b) The exemption in paragraph (a) of this section does not authorize the transfer of smelted alloy containing:

(1) Byproduct material or source material except in accordance with the requirements of Parts 30 or 40 of this chapter; or

(2) Special nuclear material other than low-enriched uranium as residual contamination except in accordance with the requirements of this part.

(c) Any person who desires to smelt scrap contaminated with low-enriched uranium or who desires to initially transfer for sale or distribution smelted alloys containing low-enriched uranium as residual contamination in the smelted alloy to persons exempt under paragraph (a) of this section or equivalent regulations of an Agreement State, should apply for a specific license issued purcuant to § 70.38, which license states that the low-enriched uranium as residual contamination in the smelted alloy may be transferred by the licensee to persons exempt under paragraph (a) of this section or equivalent regulations of an Agreement State.

§ 70.38 Specific licenses to smelt scrap or to initially transfer smelted alloys containing low-enriched uranium as residual contamination.

(a) An application for a specific license to smelt scrap contaminated with low-enriched uranium or to initially transfer for sale or distribution smelted alloys containing low-enriched uranium as residual contamination for use pursuant to § 70.15 or equivalent regulations of an Agreement State will be approved if:

(1) The applicant satisfies the general requirements of § 70.23: Provided, however, That the requirements of § 70.23(a)(3) and (4) do not apply to an application for a license to transfer low-enriched uranium in any alloy smelted pursuant to a license issued by an Agreement State.

(2) The applicant submits a description of:

(i) The history of the scrap, or the isotopic analyses performed, sufficient to provide reasonable assurance that the uranium element in or on the scrap is low-enriched uranium;

(ii) Procedures for prior decontamination of the scrap and smelting of the scrap sufficient to provide reasonable assurance that the low-enriched uranium will be residual contamination in the resulting billets, ingots, or other smelted alloy products in which the low-enriched uranium is a minor constituent less than 17.5 parts per million of representative samples of the billets, ingots, or other smelted alloy products;

(iii) Sampling procedures sufficient to demonstrate that the material taken for analysis is a representative sample of the billet, ingot, or other smelted alloy product being analyzed; and

(iv) Analytical procedures to estimate uranium concentrations with sufficient precision and accuracy to provide reasonable assurance that the uranium element is less than 17.5 parts per million of representative samples of the billets, ingots, or other smelted alloy products being analyzed.

(b) Each person licensed under paragraph (a) of this section shall file an annual report with the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, with a copy to the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter, which shall identify the type and quantity of smelted alloy produced during the reporting period and the concentrations of low-enriched uranium in the smelted alloy billets, ingots, or other products at the time of transfer of the low-enriched uranium by the licensee. If no transfers of low-enriched uranium have been made pursuant to paragraph (a) of this section during the reporting period, the report shall so indicate. The report shall cover the year ending June 30, and shall be filed within 30 days thereafter.

PART 150—EXEMPTIONS AND CONTINUED REGULATORY AUTHORITY IN AGREEMENT STATES UNDER SECTION 274

6. In 10 CFR Part 150, § 150.15(a)(6) is revised to read as follows:

§ 150.15 Persons not exempt.

(a) Persons in Agreement States are not exempt from the Commission's licensing and regulatory requirements with respect to the following activities:

* * * * *

(6) The transfer of possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing special nuclear material, source material, or byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from licensing and regulatory requirements of the Commission under Parts 30, 40, and 70 of this chapter.

* * * * *

46 FR 15278

Published 3/5/81

Comments must be received on or before 4/22/81

10 CFR Parts 30, 40, 50, 70 and 72

Decommissioning Criteria for Nuclear Facilities: Notice of Extension of Period of Comment on Draft Generic Environmental Impact Statement

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Draft generic environmental impact statement; extension of comment period.

SUMMARY: On February 10, 1981, a Notice of Availability of Draft Generic Environmental Impact Statement was published in the Federal Register [46 FR 11666] which indicated that comments must be received before March 23, 1981. Some interested persons have experienced delays in obtaining copies of the environmental impact statement. This notice extends the period of comment.

DATES: Comments must be received on or before April 22, 1981.

FOR FURTHER INFORMATION CONTACT: G. D. Calkins or Carl Feldman, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (phone 301–443–5910).

Dated at Washington, D.C. this 20th day of February 1981.

For the Nuclear Regulatory Commission.

G. D. Calkins,

Decommissioning Program Manager.

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46 FR 29712

Published 6/3/81

Comments should be submitted on or before August 3, 1981. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments re received on or before that date.

10 CFR Parts 30, 40, and 70

Upgraded Emergency Preparedness for Certain Fuel Cycle and Materials Licensees

AGENCY: Nuclear Regulatory Commission.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: One of the lessons learned from the Three Mile Island nuclear reactor accident in March 1979 was that improvements in emergency preparedness planning and coordination for some NRC licensed activities may be needed to minimize the danger to the public health and safety following an accident.

The Nuclear Regulatory Commission is, therefore, considering the adoption of regulations which will require NRC fuel cycle and materials licensees which have the potential to cause significant radiological impacts to the public from accidents to establish appropriate emergency preparedness. It is

anticipated that there will be several categories of emergency preparedness required and will therefore vary in cost and complexity dependent upon facilities' potential for accidental radiological impacts to the public, based on factors such as possession limits, potential of criticality and offsite hazards. The Commission is interested in receiving public comment on the objectives for emergency preparedness and acceptance criteria for varying categories of these NRC licensees and on impacts expected to result from the proposed rulemaking.

DATE: Comments should be submitted on or before August 3, 1981. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before that date.

ADDRESS: Written comments should be submitted to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555,

Attention: Docketing and Service Branch.

FOR FURTHER INFORMATION CONTACT: Mr. Michael Jamgochian, Division of Facility Operations, Human Engineering Section, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, (301) 443-5970.

SUPPLEMENTARY INFORMATION: One of the lessons learned from the Three Mile Island nuclear reactor accident in March 1979 was that improvements in emergency preparedness planning and coordination for some NRC licensed activities may be needed to minimize the danger to the public health and safety following an accident.

In recognition of this, strengthened requirements for emergency planning at nuclear power reactors were issued (10 CFR 50.47 and Appendix E, 10 CFR Part 50 (45 FR 55402)). Consideration is now being given to a rule change to specify strengthened emergency preparedness requirements for those fuel cycle and materials licensees which have the potential for accidents involving radioactive materials which could threaten the health and safety of the public.

A reevaluation by NRC staff of previously submitted emergency plans for fuel fabrication plants disclosed important deficiencies. For example, the plans failed to describe adequately (1) the means for the measurement and assessment of accidental releases of radioactive materials, (2) the equipment and procedures to protect workers against the types of radiation hazards that would be encountered following an accident, (3) the arrangements for prompt notification of Federal, State, and local government agencies, (4) plans for recovery actions that would restore safe conditions following an accident, and (5) emergency plans of State and local governments.

Upon noting these deficiencies and identifying other licensed activities with similar potential for accidents which could threaten the public health and safety, and which were not required to have emergency preparedness plans, the NRC staff prepared orders to require these licensees to prepare and submit comprehensive onsite radiological contingency plans. These orders, which were issued in February 1981, specifically required licensee planning for actions to be taken onsite in the event of an accident to: protect workers, limit offsite releases of radioactive materials, assess radiation doses, and mitigate adverse consequences of the accident. The orders were issued to operators of fuel processing and fabrication plants, UF_6 production plants, and radioisotope installations which possess and use significant quantities of unsealed radioactive materials. The installations selected were those which possess and use quantities of nuclear materials that might reasonably be expected to result in a potentially serious radiation exposure of an individual on or offsite as a result of a serious accident.

NUREG-0767 describes the bases used for development of the criteria for selection of the licensees issued orders. The report is included in this Federal Register Notice in order to assure adequate dissemination of relevant information.

The threshold quantities in NUREG-0767 are a preliminary effort by NRC staff to relate radioactive material license possession limits for fuel cycle and materials licensees to the offsite radiation doses established as Protective Action Guides (PAGs) by the Environmental Protection Agency. The (PAG) doses which may trigger protective actions are 1 rem to the whole body, 5 rems to the thyroid and 3 rems to any other critical organ in the case of individuals offsite. One rem to the whole body and 5 rems to the thyroid are the minimum doses which may trigger protective actions suggested by the Environmental Protection Agency in their PAGs, EPA-520/1-75-001. Three rems to other vital organs is an equivalent criterion. Doses constituting significant overexposures of workers are at least 5 times greater than those, i.e., about 5 rems whole body, about 25 rems thyroid and about 15 rems to other critical organs.

NRC believes it necessary now to codify the onsite radiological emergency planning requirements set forth in the orders, to possibly extend them to uranium mills and to other source materials licensees, as appropriate, and to specify several categories of offsite emergency preparedness requirements using factors such as possession limits, potential of criticality and offsite hazards for all of the NRC licensees whose radioactive material possession limits and processes are such that accidents could result in (i) serious radiation overexposures of workers from a release of radioactive materials, (ii) offsite radiation doses exceeding offsite PAGs, or (iii) releases or process chemicals or other nonradioactive materials which could adversely impact the safety of licensed activities.

This rulemaking will also be responsive to a petition filed by the State of New Jersey (PRM-5010, 39 FR 15900) which requested that the emergency preparedness provisions of Appendix E of 10 CFR Part 50 be extended to licensees subject to 10 CFR Part 20 as appropriate.

In developing this Advance Notice, the NRC staff has consulted and worked in cooperation with FEMA. The staff has also met with representative from the Conference of Radiation Control Program Directors and will especially be seeking input from Agreement States.

Accordingly, requirements are being considered for rulemaking which would assure that fuel cycle and materials licensees establish and maintain appropriate emergency preparedness. The requirements being considered include:

1. The potential impacts to the public from these fuel cycle and materials licensees range from insignificant harm at the large majority of NRC materials licensees to accidents which could result in significant radiological impacts to the public near the site. The rule changes being considered would require that licensees with possession limits above certain specific threshold levels perform analyses to determine the dose to the public and the emergency preparedness appropriate for their licensed activities. A fairly large group of licensees may be affected. The doses to the public and the appropriate emergency preparedness required for various types of licensees would be determined by analysis of the form and amount of radioactive material licensed to be possessed and used throughout the facility.

2. Any NRC licensee facility which has the potential to cause offsite radiation doses to members of the public in excess of the Protective Action Guides established by EPA, would be

required to establish and maintain appropriate emergency preparedness plans, or to make process or inventory adjustments which remove or reduce the potential for such offsite effects.

3. Some licensees may be required to incorporate Emergency Planning Zone (EPZs) similar to those set forth in NUREG–0396,[1] into their emergency prepardeness program.

4. Some licensees have large quantities of process chemicals, stored fuels, and water impoundments at or near the licensee's facility. Since the emergency response to accidents associated with such facilities could be complicated by accidents involving nonradiological materials, those licensees required to have emergency plans will be required to account for all hazards to the public inherent in the licensed facility's operations including the presence, onsite and near site, of hazardous materials and conditions which might effect the emergency response to an accident involving licensed materials, or might cause a radiological accident.

The NRC is especially interested in public comments related to the following issues and questions:

1. There are approximately 8,000 NRC fuel cycle and materials licensees. Staff estimates indicate that only 1 to 2 percent of these licensees would be required to have emergency plans and fewer than one percent would be required to have plans including offsite arrangements for response and support from agencies of Federal, State and local governments. What categorization schemes would ensure that licensees needing emergency plans establish and maintain an appropriate plan but at the same time ensure that licensees who either do not need plans or need only simple plans are not required to submit unneeded information? How can the approach set out in NUREG–0767 be expanded or adopted to determine the number of categories and criteria for categories of licensees needing emergency plans?

2. How should Federal, State and local governments affected by the proposed rulemaking work together and with the licensees to ensure that NRC fuel cycle and materials licensees establish an appropriate level of emergency prepardeness? In some cases, State and local governments will be able to draw upon the work that has been done to improve emergency preparedness at nuclear power reactor sites. After TMI, there was considerable effort and assistance provided by Federal, State and local governments and the nuclear power reactor licensees to establish acceptable radiological emergency preparedness onsite and offsite. However, there are State and local governments which have no nuclear power reactors located within their jurisdictions, but do have other NRC licensees within their jurisdictions. These governments may not have benefitted from the Federal, State or licensee cooperative efforts and assistance and may, therefore, face a more difficult task if a facility in their area requires offsite planning and preparedness.

3. What basis should be used to establish Emergency Preparedness Criteria for various categories of NRC fuel cycle and materials licensees? Some fuel cycle and material licensee's facilities are located in, or adjacent to, densely populated areas where accidental radiological releases could result in exposures having public health significance. For these operations, we recognize the need to perform detailed accident analyses as part of the licensing review process and to upgrade the emergency planning for these facilities as appropriate. NUREG–0767 sets out a preliminary analytic method which could be expanded and used for selecting those licensees requiring extensive analysis, and for setting the various categories of licensees by risk.

4. Would there be significant environmental impacts from the proposed rulemaking? What form are the impacts apt to take? Is the proposed rulemaking likely to result in unduly high costs to consumers or licensees? What economic impacts may be involved in this proposal?

5. Agreement States will probably adopt emergency preparedness regulations comparable to NRC rules, but a time delay is inevitable. How can this delay be reduced, and how much delay is acceptable? There are about 12,000 nuclear activities licensed by Agreement States. How are the impacts likely to differ in Agreement States and Non-Agreement States? How large is the category of Agreement States licensees for which Agreement States licensing agencies may need to issue orders (similar to the NRC orders), to prepare emergency preparedness plans?

6. What role should the Federal Emergency Management Agency have in reviewing offsite emergency preparedness for these NRC licensees? How will FEMA/NRC/Agreement State Cooperation be structured? How will FEMA review authority apply in Agreement States?

7. Will the impacts on differing categories of licensees be small relative to the resources of the licensees or will certain processes or services provided by smaller licensees no longer be economically feasible due to high costs of meeting emergency planning requirements?

It is probable that a significant number of small entities will be affected by the upgraded emergency preparedness requirements to be developed in this rulemaking process. For this reason, the NRC will prepare an initial regulatory flexibility analysis prior to issuance of proposed rules to upgrade emergency preparedness for fuel cycle and materials licensees. In order to facilitate preparation of that analysis, the NRC is particularly seeking comment from small entities (i.e., small businesses, small organizations, and small jurisdictions as defined by the Regulatory Flexibility Act 5 U.S.C. 601 et seq.) as to how the rulemaking will affect them and how the resulting regulations may be tiered or otherwise modified to impose less stringent requirements on small entities while still adequately protecting the public health and safety. Those small entities which offer comments on how the regulations could be modified to take into account the differing needs of small entities should specifically discuss:

(a) the size of their business and how the rulemaking would result in a significant economic burden upon them as compared to larger organizations in the same business community;

(b) how the regulations being considered could be modified to take into account their differing needs or capabilities;

(c) the benefits that would accrue, or the detriments that would be avoided, if the regulations being considered were modified as suggested by the , commenter;

(d) how the regulations, being considered, if modified, would more closely equalize the impact of NRC regulations or create more equal access to the benefits of Federal programs as opposed to providing special advantages to any individuals or groups; and

(e) how the regulations being considered, if modified, would still adequately protect the public health and safety.

NUREG–0767, "Criteria for Selection of Fuel Cycle and Major Materials Licenses Needing Radiological Contingency Plans," is hereby printed in its entirety.

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[1] Copies of this document may be purchased from the Government Printing Office. Information on current prices may be obtained by writing the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Attention: Publications Sales Manager.

I. Introduction

The NRC believes there is a pressing need for upgrading of radiological contingency planning of those licensed fuel cycle and major materials facilities which exhibit the potential for accidents which could result in (1) offsite doses exceeding 1 rem to the whole body, 5 rems to the thyroid or 3 rems to other critical organs, or (2) potentially serious radiation overexposures of workers from a nuclear criticality incident or from release of radioactive materials, or (3) chemical exposures which could impact radiological safety. Radiation doses of 1 rem to the whole body and 5 rems to the thyroid are the lowest Protective Action Guides (PAGs) established by the Environmental Protection Agency for triggering a protective action in public areas following a radiation accident.

Radiological contingency planning is that part of emergency response preparedness contributed by plant operators to assure (1) that plants are properly configured to limit releases of radioactive materials and radiation exposures in the event of an accident, (2) that a capability exists for measuring and assessing the significance of accidental releases of radioactive materials, (3) that appropriate emergency equipment and procedures are provided onsite to protect workers against radiation hazards that might be encountered following an accident, (4) that notifications are promptly made to Federal, State and local government agencies, and (5) that necessary recovery actions are taken in a timely fashion to return a plant to a safe condition following an accident.

Limiting possession limits, i.e., quantities and forms of radioactive materials which can be reasonably estimated to be capable of causing, due to accidents, offsite doses equal to or greater than 1 rem total body, 5 rem thyroid or 3 rem other critical organ or potentially serious radiation exposures to workers from a criticality excursion or from release of radioactive materials, are developed in this report.

II. Summary and Conclusions

Table I is a listing of those quantities of radioisotopes, as license possession limits and conditions of use, which the NRC has determined to be of potential significant concern in the event of a major accident involving those radioactive materials.

Table I.—*Schedule of Limiting Possession Limits Arranged Alphabetically by Elements*

Radionuclides	Limiting posses-sion limits (curies)
Americium-241	0.30
Americium-242	0.30
Antimony-124	1,000
Barium-140	2,000
Cadmium-113m	1,500
Calcium-45	800
Carbon-14	1,300
Californium-252	0.30
Cesium-134	350
Cesium-137	600
Chromium-51	100,000
Cobalt-60	4,000
Copper-64	50,000
Curium-242	6.0
Curium-244	0.60
Gold-198	100,000
Hydrogen-3	6,000
Iodine-125	1.0
Iodine-129	1.0
Iodine-131	3.3
Iridium-192	90,000
Iron-55	30,000
Iron-59	2,400
Krypton-85	7,000
Manganese-54	1,500
Manganese-56	120,000
Molybdenum-99	3,000
Neptunium-237	0.20
Nickel-63	5,000
Niobium-95	5,000
Phosphorous-32	15
Plutonium-238	0.10
Plutonium-239	0.10
Polonium-210	3.2
Promethium-147	3,500
Ruthenium-103	1,500
Ruthenium-106	15,000
Scandium-46	2,500
Selenium-75	500
Silver-110m	500
Strontium-90	25
Sulfur-35	400
Tantalum-182	15,000
Technetium-99m	200,000
Thallium-204	30,000
Thulium-170	1,000
Thorium-228	0.30
Tin-113	10,000
Tin-123	1,000
Tungsten-187	5,000
Uranium-233	5.0
Xenon-133	10,000
Zinc-65	2,500
Zirconium-93	5,000
Zirconium-95	1,200

Conditions

Where a license authorizes possession of a single radionuclide in forms other than a sealed sources or special form,[2] the licensee shall prepare and submit a Radiological Contingency Plan if the authorized possession limit exceeds that quantity specified for that radionuclide in the *Schedule of Limiting Possession Limits.*

Where possession of two or more radionuclides, in forms other than as sealed sources or special form,[2] is authorized by the license, the licensee shall prepare and submit a Radiological Contingency Plan if the sum of the quotients of the authorized possession limits for individual radionuclides divided by the quantities of those radionuclides specified in the *Schedule of Limiting Possession Limits* exceeds unity.

Where the license authorizes possession of a broad range of radionuclides, e.g., any byproduct material of atomic numbers 3 through 33, inclusive, in excess of those quantities specified in Schedule A of 33.100, i.e. Type A specific licenses of Broad Scope, and in forms other than as sealed sources or special form,[2] the licensee shall prepare and submit a Radiological Contingency Plan if the quantity of any radionculide authorized, either explicitly or implicitly, exceeds that quantity specified in the *Schedule of Possession Limits* or if the sums of the quotients of those quantities explicitly or implicitly authorized divided by the quantities of those radionuclides specified in the *Schedule of Limiting Possession Limits* exceeds unity.

Licensees possessing U-235, U-233, or plutonium in any form in such quantities as to require criticality monitors and alarms in accordance with 10 CFR 70.24 are also required to prepare and submit for review Radiological Contingency Plans. Possession of large quantities of UF_6, even where no criticality hazards exist, shall also require preparation and submittal for review of Radiological Contingency Plans.

III. Discussion

Estimates of quantities of materials, which could lead to significant offsite doses and to overexposures of workers from accidents, that require protective actions have been based upon the relationship:

$$Q = \frac{D_n}{DCF_n \; R \; I}$$

Where:

Q = Limiting possession limit, i.e., the quantity of radionuclide authorized to be possessed and assumed subject to an accidental release

D_n = Doses requiring protective actions, rem

DCF_n = The inhalation dose conversion factor and the limiting body organ

R = Release fraction likely to be dispersed in a severe real accident

I = Intercept fraction that could be inhaled by an individual

For the purposes of selecting licensees to prepare and submit Radiological contigency Plans it is necessary to base the selection criteria upon the authorized possession limits since we have no other information available upon which to base a conclusion that lesser quantities of radionulides would be subject to the same severe accident condition.

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[2] See 10 CFR 30.4(r) and 10 CFR 71.4(o) for definitions of "sealed source" and "special form."

Doses requiring protective actions are 1 rem to the whole body, 5 rems to the thyroid and 3 rems to any other critical organ in the case of individuals offsite. One rem to the whole body and 5 rems to the thyroid are the minimum doses requiring protective actions by the Environmental Protection Agency in their Protective Action Guides (PAGs), EPA–520/1–75–001. Three rems to other vital organs is an equivalent criterion. Doses constituting significant overexposures of workers are at least 5 times greater than those, i.e., about 5 rems whole body, about 25 rems thyroid and about 15 rems to other critical organs.

Selection criteria are based upon inhalation limiting doses except for Xe-133 and Kr-85 where submersion is the acute exposure pathway for which preplanned protective actions are needed. Ingestion pathways are not likely to cause prompt acute exposures to individuals and are believed not to the limiting in this analysis.

Rigorous estimates of release fractions, i.e., those portions of inventories of radioactive materials that could be made airborne in an accident, require plant-specific analyses to discover and characterize possible accident scenarios and to estimate possible releases. Insufficient data are presently available to support such analyses. In the absence of such data, release fractions have been estimated based upon experience and the generic physical and chemical forms of the radionuclides normally involved. Encapsulated materials and materials in "special form" have been assumed to be nondispersible and to have zero release fractions. Stable solid monolithic materials known to be accompanied by finely divided materials in industrial manufacturing operations, viz. Ir-192 and Co-60 have been assigned release fractions of 0.001. Other solids and liquids have been assigned release fractions of 0.01. Semi-volatiles have been assigned to release fractions of 0.03 and volatile and/or combustible radionuclides have been assigned release fractions of unity.

Only a fraction of the materials released, the "intercept fraction," will likely be inhaled and contribute to radiation dose. An intercept fraction of 10^{-6} for offsite exposures has been mentioned repeatedly in the literature [3] [4] and corresponds to a breathing rate of 20 m^3/day and an atomospheric relative concentration value, X/Q, of 4×10^{-3} sec/m^3, where the receptor is present throughout the entire release event. An atomospheric relative concentration value of 4×10^{-3} is believed to be an appropriately typical value for fuel cycle and materials licensee installations. This corresponds to the ground level relative concentrations experienced 150 meters from a ground level release under stable conditions. Workers could subjected to higher concentrations but only for short periods since they leave the scene of the accident or don protective equipment soon after any large releases occur.

The details of the estimation of Limiting Possession Limits are presented in Table II.

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[3] Allen Brodsky, "Resuspension Factors and Probabilities of Intake of Material in Process (or "Is 10^{-6} a Magic Number in Health Physics?"), Health Physics, Volume 39, No. 6, December 1980, pp. 992–1000.

[4] Allen Brodsky, "Determining Industrial Hygiene Requirements for Installations Using Radioactive Materials," American Industrial Hygiene Association Journal, Volume 26, May-June, 1965, pp. 294–310.

Table II Development of schedule of limiting possession limits

Isotope	Inhalation dose conversion factor[1] for total body	Inhalation dose conversion factor[1] for thyroid	Inhalation dose conversion factor[1] for other critical organ	Other critical organ[1]	Dispersibility factor, DF	$\frac{1}{DCF_{TB}\times 1000\times DF}$ *	$\frac{5}{DCF_{thyroid}\times 1000\times DF}$ *	$\frac{3}{DCF_{other}\times 1000\times DF}$ *	Limiting possession limit, Curies
H-3	1.58E-07 mrem/pCi	1.58E-07 mrem/pCi	1.58E-07 mrem/pCi	All	1	6.33E03	>6.33E03	>6.33E03	6,000
C-14	4.26E-07	4.26E-07	2.27E-06	Bone	1	2.35E03	>2.35E03	1.32E03	1,300
P-32	6.26E-06		1.65E-04	Bone	1	1.60E02		18.2	15
S-35	1.95E-06[3]		7.68E-06	Testes	1	5.13E02		3.91E02	400
Ca-45	8.02E-06[3]		3.65E-04[3]	Bone	0.01	1.25E04		8.22E02	800
Sc-46	3.11E-05		1.07E-04	Liver	0.01	3.22E03		2.80E03	2,500
Cr-51	1.25E-08	7.44E-09	1.80E-06	Lung	0.01	8.00E06	>8.00E06	1.67E05	150,000
Mn-54	7.87E-07		1.75E-04	Lung	0.01	1.27E05		1.71E03	1,500
Mn-56	2.29E-11		2.53E-06	GI-LLI	0.01	4.37E09		1.19E05	120,000
Fe-55	4.93E-07		9.01E-06	Lung	0.01	2.03E05		3.33E04	30,000
Fe-59	1.32E-06		1.27E-04	Lung	0.01	7.58E04		2.36E03	2,400
Co-60	1.85E-06		7.46E-04	Lung	0.001	5.41E05		4.02E03	4,000
Ni-63	1.81E-06		5.40E-05	Bone	0.01	5.57E04		5.55E03	5,000
Cu-64	7.69E-11		6.12E-06	GI-LLI	0.01	1.30E09		4.90E04	50,000
Zn-65	5.82E-06		1.08E-04	Lung	0.01	1.72E04		2.78E03	2,500
Se-75	1.48E-06[3]		5.33E-06[3]	Kidneys	1	6.76E02		5.63E02	500
Kr-85	Submersion[4]								7,000
Sr-90+D	7.62E-04		1.24E-02	Bone	0.01	1.31E02		2.42E03	25
Zr-93+D	1.37E-06		5.22E-05	Bone	0.01	7.30E04		5.75E03	5,000
Zr-95+D	2.91E-06		2.21E-04	Lung	0.01	3.44E04		1.36E03	1,300
Nb-95	5.26E-07		6.31E-05	Lung	0.01	1.90E05		4.75E03	5,000
Mo-99+D	2.87E-09		3.10E-05	GI-LLI	0.03	1.16E07		3.23E03	3,000
Tc-99m	4.63E-12		5.20E-07	GI-LLI	0.03	7.20E09		1.92E05	200,000
Ru-103+D	8.23E-08		6.31E-05	Lung	0.03	4.05E05		1.58E03	1,500
Ru-105+D	3.89E-11		6.02E-06	GI-LLI	0.03	8.57E08		1.66E04	15,000
Ag-110m+D	7.43E-07		5.79E-04	Lung	0.01	1.35E05		5.18E02	500
Cd-113m	4.97E-06		2.08E-04	Lung	0.01	2.01E04		1.44E03	1,500
Sn-113	2.53E-06[3]	7.06E-07[2]	3.11E-05[3]	Bone	0.01	3.95E04	7.08E05	9.65E03	10,000
Sn-123	9.82E-07	5.67E-07	2.88E-04	Lung	0.01	1.02E05	8.81E05	1.04E03	1,000
Sb-124	1.55E-06	9.44E-09	3.10E-04	Lung	0.01	6.45E04	5.30E07	9.68E02	1,000
I-125		5.9E-04[2]			1		8.47		8.0
I-129	6.91E-06	5.54E-03			1	1.45E02	9.02E-01		1.0
I-131+D	2.56E-06	1.49E-03			1	3.90E02	3.36		3.3
Xe-133	Submersion[4]								10,000
Cs-134	9.10E-05		1.06E-04	Liver	0.03	3.66E02		9.43E02	350
Cs-137+D	5.35E-05		7.76E-05	Liver	0.03	6.23E02		1.29E03	600
Ba-140+D	3.21E-07		1.59E-04	Lung	0.01	3.12E05		1.89E03	2,000
Pm-147	3.19E-06		8.37E-05	Bone	0.01	3.13E04		3.58E03	3,500
Tm-170	9.52E-06[3]		3.22E-04[3]	Bone	0.01	1.05E04		9.32E02	1,000
Ta-182	2.19E-05[3]		1.70E-04[3]	Liver	0.001	4.57E04		1.76E04	15,000
W-187	3.10E-10		1.94E-05	GI-LLI	0.03	1.08E08		5.15E03	5,000
Ir-192	5.46E-06[3]		5.13E-05[3]	Kidneys	0.001	1.83E05		5.85E04	50,000
Au-198	4.74E-07[3]		2.43E-06[3]	Kidneys	0.01	2.11E05		1.23E05	100,000
Tl-204	6.28E-07[3]		1.03E-05[3]	Kidneys	0.01	1.59E05		2.91E04	30,000
Po-210	9.58E-05		3.14E-02	Lung	0.03	3.48E02		3.18	3.2
Th-228+D	6.77E-03		1.01	Lung	0.01	1.48E01		2.97E-01	0.30
U-233+D	6.60E-04		5.32E-02	Lung	0.01	1.52E02		5.64	5.0
Np-237+D	6.87E-02		1.69	Bone	0.01	1.46		1.78E-01	0.20
Pu-238	6.90E-02		2.74	Bone	0.01	1.45		1.09E-01	0.10
Pu-239	7.75E-02		3.19	Bone	0.01	1.29		9.40E-02	0.10
Am-241	6.71E-02		1.01	Bone	0.001	1.49		2.97E-01	0.30

Table II (Continued)

Isotope	Inhalation dose conversion factor[1] for total body	Inhalation dose conversion factor[2] for thyroid	Inhalation dose conversion factor[3] for other critical organ	Other critical organ[1]	Dispersibility factor, DF	$\frac{1}{DCF_{TB}\times 1000\times DF}$ *	$\frac{5}{DCF_{thyroid}\times 1000\times DF}$ *	$\frac{3}{DCF_{other}\times 1000\times DF}$ *	Limiting possession limit, Curies
Am-241	6.57E-02		1.01	Bone	0.01	1.52		2.97E-01	0.30
Cm-242	9.64E-04		3.92E-02	Lung	0.01	1.02E02		7.65	8.0
Cm-244	3.51E-02		5.90E-01	Bone	0.01	2.85		5.08E-01	0.50
Cf-252	2.33E-02		9.78E-01	Bone	0.01	4.29		3.07E-01	0.30

*Possession Limits determined using INTERCEPT Factor of 10^{-6}

[1] Inhalation dose conversion factors for adults, mrem/pCi, from NUREG-0172, Age-Specific Radiation Dose Commitment Factors for a One-Year Chronic Intake, Table 8, (DACRIN).

[2] Inhalation dose conversion factors for adults, mrem/pCi, where W solubility class and AMAD = 1 μm are assumed, DACRIN.

[3] Inhalation dose conversion factors for adults, mrem/pCi, from ORNL-4992, A Methodology for Calculating Radiation Doses from Radioactivity Released to the Environment, Table 4.2, (INREM).

[4] Calculated for submersion in a semi-infinite cloud taking $X/Q = 10^{-8}$ and with dose factors from Regulatory Guide 1.109, Calculation of Annual Doses to Man from Routine Releases of Reactor Effluents for the Purpose of Evaluating Compliance with 10 CFR 50, Appendix I, Table B-1.

Nuclide	DF^{β}_{skin}, $\frac{mrad}{pCi.yr}$	DF^{γ}_{air}, $\frac{mrem}{pCi.yr}$	DFB^{γ}, $\frac{mrem}{pCi.yr}$
Kr-85	1.34E-03	1.72E-05	1.61E-05
Xe-133	3.06E-04	3.53E-04	2.94E-04

$$\text{Skin dose} = 31.7Q\ X/Q(DF^{\beta}_{skin} + 1.11\ DF^{\gamma}_{air})$$

$$\text{Body dose} = 31.7Q\ X/Q\ DFB^{\gamma}$$

$$\text{For skin dose, } Q = \frac{3}{31.7\ X/Q\ (DF^{\beta}_{skin} + 1.11\ DF^{\gamma}_{air})}$$

$$\text{Kr-85, skin dose} = \frac{3}{31.7 \times 0.01\ (1.34E\text{-}03 + 1.11 \times 1.72E\text{-}05)}$$

$$= 6.96E03\ Ci$$

$$\text{Xe-133, skin dose} = \frac{3}{31.7 \times 0.01\ (3.06E\text{-}04 + 1.11 \times 3.53E\text{-}04)}$$

$$= 1.36E04$$

$$\text{For body dose, } Q = \frac{1}{31.7 \times X/Q\ DFB^{\gamma}}$$

$$\text{Kr-85, body dose} = \frac{1}{31.7 \times 0.01 \times 1.61E\text{-}05}$$

$$= 1.96E05$$

$$\text{Xe-133, body dose} = \frac{1}{31.7 \times 0.01 \times 2.94E\text{-}04}$$

$$= 1.07E04$$

For Kr-85, skin dose is limiting and Q = 7,000 Ci
For Xe-133, body dose is limiting and Q = 10,000

(Sec. 161b. i., and o., Pub. L. 83–703, 68 Stat. 948 (42 U.S.C. 2201) Sec. 201, as amended, Pub. L. 93–438, 88 Stat. 1242, Pub. L. 94–79, 89 Stat. 413 (42 U.S.C. 5341))

Dated at Washington, D.C., this 28th day of May 1981.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

50 FR 5600
Published 2/11/85
Comment period expires 5/13/85

10 CFR Parts 30, 40, 50, 51, 70 and 72

Decommissioning Criteria for Nuclear Facilities

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission is proposing amendments to its regulations that would set forth technical and financial criteria for decommissioning licensed facilities. The proposed amendments address decommissioning planning needs, timing, funding mechanisms, and environmental review requirements. The intent of the proposed amendments is to assure that decommissioning of all licensed facilities will be accomplished in a safe and timely manner and that adequate licensee funds will be available for this purpose. The proposed rule also contains a response to a petition for rulemaking (PRM-50-22), concerning decommissioning financial assurance, initially filed by the Public Interest Research Group (PIRG), et al. on July 5, 1977.

DATE: Comments must be received on or before May 13, 1985.

Comments received after this date will be considered if it is practical to do so. Assurance of consideration is possible only if comments are received on or before this date.

ADDRESSES: Submit written comments to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch. Copies of comments received and the generic environmental impact statement may be examined in the Commission's Public Document Room at 1717 H Street NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Keith G. Steyer or Catherine R. Mattsen, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 443-7910.

SUPPLEMENTARY INFORMATION:

Background

On March 13, 1978, the Commission published an Advance Notice of Proposed Rulemaking in the **Federal Register** (43 FR 10370) stating that the Commission was reevaluating its decommissioning policy and considering amendments to its regulations to provide more specific requirements relating to the decommissioning of nuclear facilities. The plan for the reevaluation included the development of an information base and the preparation of a generic environmental impact statement (GEIS), and based on these, the development of proposed amendments to the regulations. The information base for rulemaking is essentially complete and consists primarily of a series of NUREG/CR reports on studies of the technology, safety, and costs of decommissioning various kinds of nuclear facilities. These reports were prepared by Battfle Pacific Northwest Laboratories (PNL).[1] On February 10, 1981, the Commission announced the availability of the draft GEIS for public comment (46 FR 11666). Section 15 of the draft GEIS recommends certain policy considerations. These recommendations, as modified by comments received on the draft GEIS and other sources, provide the basis for the proposed amendments to the Commission's regulations. The proposed amendments cover a number of topics related to decommissioning. However, acceptable levels of residual radioactivity for release of property for unrestricted use are not being proposed as part of this rulemaking. This issue will be dealt with in a separate rulemaking action which will propose amending 10 CFR Part 20 to specify limits of residual radioactivity for decommissioning.

In the course of this reevaluation, the staff has maintained a dialouge with the States and the public during the early, formative time of decisionmaking on critical issues. Preliminary staff positions on the major decommissioning issues have been presented in staff (NUREG) reports.[2]

Decommissioning as defined in this proposed rule means to remove nuclear facilities safely from service and reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of license. For the purposes of this proposed rule, the term "nuclear facilities" is used to refer to the site, buildings and contents, and equipment associated with any NRC licensed activity.

Decommissioning activities are initiated when a licensee decides to terminate licensed activities. If nuclear facilities are to be reused for nuclear purposes, applications for license renewal or amendment or for a new license are submitted according to the appropriate existing regulation. Reuse of a nuclear facility for other nuclear purposes is not considered decommissioning.

These proposed amendments apply to decommissioning of power reactors, nonpower reactors, fuel reprocessing plants, fuel fabrication plants, uranium hexafluoride production plants, independent spent fuel storage installations, and non-fuel-cycle nuclear facilities. The decommissioning of uranium mills and mill tailings, low-level waste burial facilities, or high-level waste repositories, has been treated in separate regulatory actions. However, the general technical criteria in this proposed rule will apply to uranium mills in addition to the technical and financial criteria contained in Appendix A or Part 40.

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[1] A bibliography of these reports and other background documents is included at the end of the Supplementary Information. These documents are available for inspection and copying for a fee in the Commission's Public Document Room at 1717 H Street NW., Washington, DC 20555.

[2] Ibid.

The proposed amendments apply to nuclear facilities that operate through their normal lifetime, as well as to those that may be shut down prematurely. It is expected that nearly all facilities will operate through their normal lifetime. However, the activities following premature shutdown of a facility as a result of an accident are somewhat different than those of a routine decommissioning. There are three stages involved: a stabilization period, during which accident conditions are brought under control if necessary; an accident cleanup period; and a decommissioning period. During the accident cleanup, the major portion of contamination resulting from the accident is cleaned up and the associated wastes are processed. Following accident cleanup, the facility may either be recovered for reuse or be decommissioned. A detailed study of reactor decommissioning following accident cleanup (NUREG/CR-2601—Reference 7) indicated that there may be differences in some of the specific aspects of decommissiong such as the spread of contamination, waste volumes, exposures, and costs. However, the report also indicates that the technology exists to accomplish the decommissioning and that the safety and costs of decommissioning following the accident cleanup do not vary significantly from that following normal operations.

Current regulations cover the requirements and criteria for decommissioning in only a limited fashion. Although decommissioning is not an imminent health and safety problem, specific requirements related to decommissioning have had to be determined on a case-by-case basis. Revision of current regulations is necessary to clarify these requirements and to provide for consistent and efficient regulatory actions related to decommissioning. The necessary amendments could be issued as a new part of the Commission's regulations. However, the policy developed as a result of the reevaluation will directly affect licensing activities under 10 CFR Parts, 30, 40, 50, 51, 70, and 72. Accordingly, amendments to each of these parts, rather than a new part, will facilitate use by NRC staff and licensees.

Classes of facilities licensed under Parts 50 and 72 are considered major facilities all of which will require a significant decommissioning effort. Activities licensed under Parts 30, 40, and 70 however, cover a wide range. Termination of the majority of these licenses requires relatively simple decommissioning procedures. For these reasons it was necessary to take a somewhat different regulatory approach in these parts to implement the same generic policy.

Description of Policy and Proposed Rule

Five major issues evolved from the policy reevaluation, namely decommissioning alternatives, timing, planning, financial assurance, and residual radioactivity. In addition, it became apparent that environmental review requirements could be reduced. These subjects are discussed in the following paragraphs.

A. Decommissioning Alternatives

More than one alternative method of decommissioning may be acceptable depending on the type of radioactive contamination present at shutdoun and other factors. The proposed rule indicates that use of alternatives in which unrestricted release is postponed for a significant period of time following cessation of operations would be acceptable in cases where sufficient benefit results. Possible benefits include such things as reduction in occupational exposure or waste volume. Alternatives and factors affecting their acceptability will be dealt with in a revision of Regulatory Guide 1.86 on termination of licenses for nuclear reactors, and in a similar document to be developed for materials facilities.

The alternatives considered are essentially the same as those which have been used in the past except that they have been redefined to include all activities leading to termination of license in keeping with the definition of decommissioning contained in this proposed rule.

B. Timing

Timing refers to the length of the decommissioning period, that is, the time from permanent cessation of operations to license termination. Each type of nuclear facility has characteristic radionuclides that will affect the selection of the decommissioning alternative and the length of time acceptable to delay license termination. These proposed rules require that decommissioning begin shortly after permanent cessation of operations and significant delays in completion of decommissioning would be acceptable if there is some compensating benefit. Beyond this, factors affecting timing will be considered in the related regulatory guides to be issued, since the acceptability of alternatives and overall timing may involve case-by-case considerations.

C. Planning

Preliminary planning at the licensing stage and over facility life is important to ensure that decommissioning can be accomplished safely. Information on funding methods for providing financial assurance for decommissioning will be submitted with applications for new licenses for production and utilization facilities. For existing licenses under Part 50, this information will be submitted within a reasonable period of time after the rule becomes effective. The time period suggested in this proposed rule is two years. This information will consist of a cost estimate for decommissioning either as prescribed in the regulations or as estimated by the applicant or licensee and a description of the method of assuring funds for decommissioning. Part 50 licensees will also submit an updated cost estimate and, if necessary, plans for adjusting funding levels 5 years before the projected end of operation. Applicants for independent spent fuel storage installation (ISFSI) licenses will include plans for providing financial assurance for decommissioning in a decommissioning plan submitted at licensing as is currently required.

Similarly, some material licensees licensed under Parts 30, 40, and 70 will either provide financial assurance in prescribed amounts or submit a decommissioning funding plan showing the basis for a proposed amount. Details of financial assurance requirements are discussed in the next section.

Licensees under Parts 30, 40, 50, 70, and 72 will be required to keep records which could be important at the time of decommissioning. Relevant records, as specified in the proposed rule, consist of records of spills or other unusual occurrences from which significant contamination may remain and design specifications, in the form of drawings if available, of areas of high radiation or potential inaccessible contamination. The proposed rule would require a separate file for information important to decommissioning but would allow the use of references to records kept for other purposes.

Applicants and licensees should also consider other aspects of operating procedures as well as design features which could facilitate decommissioning as part of overall programs to protect the health and safety of the public and to keep radiation exposures and effluents "as low as reasonably achievable," however, no specific requirements would be added to the regulations.

Decommission plans will be submitted by all Parts 50 and 72 licensees at the time of written notification that the licensee desires to terminate the license as is the current licensing practice. This proposed rule would require that this notification be made within two years following permanent cessation of operation or one year prior to license expiration, whichever occurs first. For Part 50 licensees, the present practice of also applying for an amendment to restrict operation of the facility would continue. The amendment changes the operating license to what is referred to as a "possession only" license, under which required controls and limits are modified as appropriate to planned procedures. Licensees under Parts 30, 40, and 70 engaged in activities resulting in major decommissioning considerations will also submit plans for completion of decommissioning. These will be required if a potential for significant health and safety impacts exists and will be submitted promptly after the end of optional activities and prior to the license expiration date. Decommissioning plans will contain sufficient detail to demonstrate that decommissionig can be accomplished safely. Major elements of decommissioning plans are specified in the proposed rules. Additional guidance will be made available in planned regulatory guides on standard format and content of decommissioning plans.

In addition to specifying decommissioning plans, other amendments related to license termination are proposed for Parts 30, 40, and 70 primarily for clarifty and uniformity. These changes would somewhat modify the procedures established for the termination of a license contained in a final rule published on July 15, 1983 (48 FR 32324). The requirement for notification of intent to terminate licensed activities contained in existing paragraph (c) of §§ 30.36, 40.42, and 70.38 will be removed. Although it may be practical in most cases for operational activities to cease and initial cleanup and survey to completed at least 30 days prior to license termination, the requirement as it exists may result in licensees submitting a separate notification of intention not to renew 30 days prior to expiration plus the submission of information concerning residual contaimination sometime in the next 30 days. This separate notification is not considered necessary.

Additional modifications to the requirements contained in existing paragraphs (d) (2) and (3) of §§ 30.36, 40.42, and 70.38 are made to insert the standard for submission of decommissioning plans and to clarify—

1. That, whether or not the licensee has detected residual radio-activity, the licensee is responsible for controlling the site until the Commission terminates the license; and

2. That, in all cases, the same standards for termination of license apply, as stated in proposed paragraph (f) of §§ 30.36, 40.42, and 70.38: that radioactive material has been properly disposed of, reasonable effort has been made to remove any residual contamination, and information exists which demonstrates that the premises are suitable for release for unrestricted use.

D. Financial Assurance

The objective of the proposed rule on financing the decommissioning of nuclear facilities is to require licensee to provide reasonable assurance that adequate funds are available to ensure that decommissioning can be accomplished in a safe manner and that lack of funds does not result in delays that may cause potential health and safety problems. The licensee is responsible for completing decommissioning in a manner that protects health and safety.

There are several different methods for providing financial assurance. Because of the variety of facility types and licensee financial situations, different methods are considered acceptable for providing reasonable assurance of the availability of funds. The funding methods specified in the proposed rule meet the criteria respecting assurance and cost which are described more fully under the subject heading "Criteria for Funding Methods."

Information on funding methods will be provided by all applicants for operating licenses and existing licensees for production and utilization facilities. For electric utility applicants and licensees, the amount of funds assured can be based either on an amount prescribed in the regulations, or on a facility-specific cost estimate submitted as part of a decommissioning funding plan. The amount[3] proposed is $100,000,000 (1984 dollars) adjusted for inflation at a rate two times the change in the Consumer Price Index published by the U.S. Department of Labor, Bureau of Labor Statistics. Plans for financial assurance for decommissioning are already required for independent spent fuel storage installations.

Certain applicants and existing licensees under Parts 30, 40, and 70 will also be required to submit a decommissioning funding plan. The rule specifies that funding plans will be required of licensees authorized to use unsealed materials of half-life greater than 120 days in quantities exceeding 10^5 times the applicable quantities in Appendix C of Part 20. The note to Appendix C concerning the "rule of ratios" used for purposes of § 20.303 is not applied in this case. For the purposes of this requirement, plated foils would not be considered unsealed material. In Part 40, the funding plan requirement applies to licensees authorized to use more than 10 mCi of source material in a readily dispersible form. If the license authorizes processing of materials, although initially sealed or non-dispersible, the processing would be assumed to result in unsealed or readily dispersible material. These licensees will have the following options: (1) Submitting the funding plan within one year following the effective date of the final rule or (2) submitting a certification of financial assurance for decommissioning in an amount of at least $500,000, within one year of the effective date of the final rule, deferring the funding plan until application for renewal is made. Financial assurance requirements for mills are contained in Appendix A to Part 40 and are not covered by this proposed rule.

Certain other materials licensees will be required to submit either a certification that a means of assuring funds in a prescribed amount has been provided or a decommissioning funding plan. Licensees using between 10^4 and 10^5 times Appendix C values of unsealed byproduct or special nuclear material must provide assurance of funds in the amount[3] of $500,000 or submit a decommissioning funding plan. Licensees using between 10^3 and 10^4 times Appendix C values of unsealed byproduct or special nuclear material or between 10 mCi and 100 mCi of source material in readily dispersible form must provide assurance of funds in the amount[3] of $100,000 or submit a funding plan. Licensees using sealed sources containing byproduct material in quantities exceeding 10^{10} times Appendix C values must provide assurance of funds in the amount[3] of $50,000 or submit a funding plan.

This proposed rule specifies acceptable funding methods in the appropriate sections for various types of licensees. In order to assure that the funds will be adequate at the time of decommissioning, the proposed rule provides that decommissioning funding plans include provisions for adjusting cost estimates and associated funding levels over the life of the facility and that in the case of Part 50 licensees an update cost estimate be submitted specifically at about 5 years prior to the projected end of operation. Additional guidance on financial assurance is also planned to be provided in regulatory guides.

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[3] The bases for selecting this prescribed amount and those noted below for materials facilities are described more fully under the subject heading "Mechanisms for Requiring Financial Assurance."

At the time of final shutdown, or cessation of operations, decommissioning plans, when required, will provide an updated, more accurate cost estimate, and some adjustment may need to be made in the decommissioning fund. Parts 50 and 72 specifically state that if an alternative is chosen which significantly delays completion of decommissioning, means must be included to continue periodic review and adjustment of funding level over the extended decommissioning period. In Part 50, where internal reserve is allowed for utilities during operation, it is specifically required that the funds be placed in an account separate from licensee assets during the prolonged decommissioning period or that assurance be provided by a surety or insurance method.

E. Residual Radioactivity

A primary objective after permanent cessation of operations is authorized termination of a license. For all facilities covered by this rule, all premises must be suitable for release for unrestricted use before a license can be terminated. To release property for unrestricted use a permissible level of residual radioactivity must be established. These levels are not proposed in this rule, but are being developed in a separate rulemaking action. In the past, limits have been provided as guidance in such documents as Regulatory Guide 1.86, and have sometimes been determined on a case-by-case basis.

F. Environmental Review Requirements

The proposed rule would reduce the environmental review requirements (National Environmental Policy Act of 1969, as amended) related to decommissioning by amending Part 51.

The overall impacts of decommissioning would continue to be addressed in the environmental reviews for the licensing of major facilities. No additional detail would specifically be required. Except to the extent required by special circumstances, preparation of environmental impact statements for the decommissioning of production and utilization facilities and independent spent fuel storage installations would no longer be required. Instead, in accordance with the procedures in the recently revised Part 51 of the Commission's regulations, an environmental assessment would be prepared. This environmental assessment would supplement the environmental impact statements previously prepared in connection with the issuance of the construction permit and operating license for the facility. It should be noted that pursuant to criteria in revised 10 CFR Part 51 environmental assessments may result in a conclusion that an environmental impact statement is required in the particular circumstances of the proposed Federal action. Information concerning environmental impacts of decommissioning would be submitted by the licensee in a supplement to environmental reports previously submitted. Environmental impact statements would continue to be required for the decommissioning of waste disposal facilities only.

The proposed rule also indicates that there would be no additional environmental review requirements connected with the new decommissioning requirements, specifically, that approval of decommissioning funding plans be categorically excluded from requirements for environmental impact statements or environmental assessments.

Rational for the Proposed Rule Changes

A. Decommissioning Alternatives

Decommissioning alternatives are categorized into three major classifications which are referred to as DECON, SAFSTOR, and ENTOMB. This terminology was introduced to reduce the confusion and misunderstanding that existed with the previous terms used to designate decommissioning alternatives. These terms have the following meanings:

DECON is the alternative in which the equipment, structures, and portions of a facility and site containing radioactive contaminants are removed or decontaminated to a level that permits the property to be released for unrestricted use shortly after cessation of operations.

SAFSTOR is the alternative in which the nuclear facility is placed and maintained in such condition that the nuclear facility can be safely stored and subsequently decontaminated (deferred decontamination) to levels that permit release for unrestricted use.

ENTOMB is the alternative in which radioactive contaminants are encased in a structurally long-lived material, such as concrete. The entombed structure is appropriately maintained and continued surveillance is carried out until the radioactivity decays to a level permitting unrestricted release of the property. This alternative would be allowable for nuclear facilities contaminated with relatively short-lived radionuclides such that all contaminants would decay to levels permissible for unrestricted use within a period on the order of 100 years.

Based on an analysis of the technical data base, decommissioning can be accomplished safely and at reasonable cost shortly after cessation of facility operation. DECON has certain benefits in that it would prepare the property for unrestricted use in a much shorter time period than SAFSTOR or ENTOMB with acceptable effects on occupational and public health and safety. Completing decommissioning and releasing the property for unrestricted use eliminates the potential problems that may result from an increasing number of sites contaminated with radioactive material, as well as eliminating potential health, safety, regulatory, and economic problems associated with maintaining the nuclear facility. The use of DECON assumes the availability of capacity to handle waste requiring disposal. The Federal and State governments have activities underway to assure that there will be this capacity.

Delay in the completion of decommissioning, as in the case of SAFSTOR or ENTOMB, would be acceptable primarily for reasons of occupational health and safety, since it is recognized that with delay there will be reduction in occupational dose and radioactive waste volume for some nuclear facilities due to radioactive decay. In addition, SAFSTOR may have some advantage where there are other operational nuclear facilities at the same site, and may also become necessary in other cases if there is a shortage of radioactive waste disposal space offsite. The appropriate delay will depend on the type of facility and the contaminant isotopes involved, but should not be greater than about 100 years as this is considered a reasonable time period for reliance on institutional control (Ref. 19). One of the difficulties with ENTOMB for any complex structure such as a reactor is that the radioactive materials remaining in the entombed structrue would need to be characterized well enough to be sure that they will have decayed to acceptable levels at the end of the surveillance period (up to about

100 years). If this cannot be done adequately deferred decontamination would become necessary, which could make ENTOMB more difficult and costly than DECON or SAFSTOR.

B. Timning

The issue of timing concerns what amount of time would be appropriate to allow for completion of decommissioning including the entire period between final shutdown and license termination. The primary consideration is the decay of radioactivity which may result in reductions in occupational exposure and waste needing disposal. Facilities differ regarding the particular radionuclides most critical to decommissioning. For light water power reactors Co-60, with a half-life of 5.3 years, is the nuclide that has the most effect on decontamination efforts and is referred to as the critical/abundant nuclide. Other isotopes that can affect decommissioning efforts are Cs-137 (30-year half-life) and the long-lived isotopes Nb-94 and Ni-59.

As discussed above, a review of the technical data shows that, for DECON, occupational exposure can be kept reasonable. For example, studies indicate that occupational doses from decommissioning light water power reactors would be about 400 man-rem per year (1200–1900 man-rem over 4–5 years for large ractors). This is gnerally less than current annual doses at operating reactors. SAFSTOR will result in reduced occupational dose and amount of radioactively contaminated waste. Based on the half-life of the critical/abundant nuclide, the reduction of occupational doses beyond about 30 years would be marginally significant although a significant volume reduction in contaminated waste would result from 50 years in safe storage. It appears that DECON or 30 to 50 year SAFSTOR are reasonable options for decommissioning a light water power reactors. Generally for reactors, the overall impact of either of these alternatives is similar, with the lower occupational dose and wastes with SAFSTOR compensating for the costs and uncertainties of controlling the site for a long period. The choice of alternative in individual cases will depend on a number of factors specific to the particular reactor, site, and time of decommissioning, for example, a longer SAFSTOR period may be acceptable if the safety of an adjacent reactor might be affected by dismantlement procedures.

With regard to the ENTOMB alternative, long-lived activation products contained in reactor internals, such as Nb-94 and Ni-59, would probably preclude the use of ENTOMB for power reactors unless reactor internals were removed. If reactor internals are removed, some method would have to be provided to demonstrate that the entombed radioactivity will decay to levels permitting release of the property for unrestricted use within about 100 years, which, as noted above, would be difficult.

For research and test reactors and ISFSIs, occupational doses would be much less significant and much easier to manage than for power reactors. Thus, DECON is considered the most reasonable option. SAFSTOR could be justified in some cases. ENTOMB is not expected to be visble for ISFSIs and is also unlikely to be a reasonable option for non-power reactors as the cost would not be justified.

For materials facilities associated with licenses under Parts 30, 40, and 70, occupational doses are also quite low in most cases, and DECON the most likely option. SAFSTOR is possible for short-lived materials, but any extended delay would rarely be justifiable. For these reasons the proposed amendments to Parts 30, 40, and 70 do not mention alternatives or have special requirements for extended delays. If after disposing of inventory and some preliminary decontamination, contamination from relatively short-lived materials is reported, the Commission will determine whether allowing a period for decay is an appropriate means of completing decommissioning. It is expected however that for most licenses under these parts it will be practical to complete decontamination to levels suitable for unrestricted release prior to reporting levels of residual radioactivity to the Commission. A survey must be carried out and reported on promptly after the end of operations and prior to the expiration of the license.

C. Planning

Planning for decommissioning is a critical item for ensuring that the decommissioning activities can be accomplished in a safe and timely manner. Development of detailed plans at the application stage is not possible because many factors (e.g., technology, regulatory requirements, economics) will change before the license period ends. Thus, most of the planning for the actual decommissioning will occur near final shutdown. However, a certain amount of preliminary planning should be done at the application stage.

Preliminary Planning

The availability of adequate funds is important in assuring that decommissioning will be carried out in a safe and timely manner. There are also aspects of design and operations that could affect decommissioning in terms of improved health and safety and reduced radioactive waste.

Information on decommissioning funding methods, described below, will be submitted with an application for an operating license for a production or utilization facility. An application for an independent spent fuel storage installation will include a decommissioning plan including financial plans as is presently required. In the case of existing Part 50 licensees, information on funding methods would need to be submitted within a reasonable time period following the effective date of this rule. This information will be provided in the form of a decommissioning funding plan or, in the case of electric utility applicants and licensees, may be provided as a certification of financial assurance. A certification will indicate that the amount prescribed in the regulation is being used and will include a description of the method of assuring funds for decommissioning. A funding plan will include an initial cost estimate and also provide a description of the method of assuring funds for decommissioning including means of adjusting cost estimates and associated funding levels over the life of the facility. The initial cost estimate is intended to provide an approximate estimate of the decommissioning cost. Initial estimates may be based on information from the literature (e.g., generic studies, licensee models, experience, etc.) which provide a reasonable estimate of the cost of decommissioning. The PNL decommissioning studies can be used for initial estimates with suitable adjustments for inflation and for site-specific factors. The proposed regulations require that over the operating life of the facility, the cost estimate be updated by the licensee periodically to take into account factors which could affect the cost of decommissioning. The rule would specifically require all Part 50 licensees to submit 5 years prior to the projected end of operation an up-to-date cost estimate on which to base financial assurance even if the certification option had been used previously. In this manner it is expected that the amounts being assured by the funding method will reach a level at the end of life which is approximately equal to the actual costs of decommissioning. In particular, the cost estimate submitted at 5 years prior to end of operation would be based on a current assessment of major factors that could affect decommissioning costs. The requirement is intended to assure that all Part 50 licensees, including those choosing the certification method, shall consider relevant, up-to-date information which could be important to adequate planning and funding for decommissioning well before decommissioning actually begins. It is expected that this requirement can ordinarily be accommodated in the provisions of a funding plan.

Acceptable methods of providing financial assurance are specified in the rule and are discussed further in the following section on financial assurances.

For most facilities associated with licenses under Parts 30, 40, and 70, decommissioning is much less involved, and has much less impact than the decommissioning of a reactor, for example. A decommissioning funding plan is being required for certain facilities where decommissioning costs could be very high. Financial assurance is also required without the submittal of a funding plan for certain other materials licensees as discussed in the next section.

The studies performed as part of the policy reevaluation have shown that facilitation of decommissioning in the design of a facility or during its operation can be beneficial in reducing operational exposures and waste volumes requiring disposal at the time of decommissioning. In addition, facilitation can improve financial assurance by keeping actual costs of decommissioning in line with the estimated costs on which the levels of financial assurance are based. Although no specific requirement is being proposed, the effects of operational procedures on decommissioning should be considered by licensees as part of their program to maintain radiation exposures and effluents "as low as reasonably achievable." The facilitation of decommissioning in the design of facilities can be considered under the general standard for issuance of license that equipment and facilities be adequate to protect the health and safety of the public contained in §§ 30.33(a)(2), 40.32(c), 50.40(a), 70.23(a)(3), and 72.31(a)(10). Suggestions for facilitation are presented in the PNL studies, including a preliminary study on facilitation of reactor decommissioning.

In particular, experience has shown that an important aspect of operation is the maintenance of adequate information on the design and current condition of the facility and site, so that decommissioning can be carefully planned and carried out. The proposed rule would specifically require that records of relevant operational information helpful in facilitating decommissioning be kept by all reactor and materials licensees. Plans should be developed to collect, maintain, and recall records and archive files which include as-built and as-revised drawings and specifications and operational occurences which could significantly affect decommissioning. The proposed rule would specifically allow the use of references to relevant information and locations in order to avoid unnecessary duplication of records kept for other purposes. The proposed rule would also specify that referencing of drawings need not include indexing of each individual relevant document. The intent of this requirement is to assure that all important information is kept until termination of license and that it be readily accessible when needed.

Final Planning

Final decommissioning planning will involve greater technical detail than preliminary planning. Decommissioning plans should be submitted in a timely way for review and approval prior to the initiation of any major decommissioning activity to avoid delay of decommissioning after shutdown. For a power reactor, review and approval could take up to a year. Thus, it would be beneficial to submit plans a year prior to planned termination of operation, if possible.

The proposed rule would require decommissioning plans for production and utilization facilities and ISFSIs to be submitted within two years following permanent cessation of operation or one year prior to operating license expiration. The decision as to whether a shutdown will be permanent is, of course, the licensee's. This provision does not limit how long a licensee may have a facility shut down under his operating license but means only that when a facility is permanently removed from operational status, plans need to be made as to how the ultimate termination of license will be attained. Upon approval of the plans, the license will be modified to reflect the approved decommissioning alternative authorizing continued possession until the approved alternative has been carried out. This reflects current licensing practice. For reactors which have permanently shut down prior to the effective date of the final rule, no time limit is given for application for license termination and no additional planning is specifically required until such application is made. However, the Commission may require additional planning, particularly in the area of financial assurance, on a case-by-case basis as appropriate or practical for partially decommissioned facilities in line with the policy represented by this rule if made effective.

The level of detail required would be appropriately less for the delayed decontamination activities if SAFSTOR is the proposed alternative, however, preliminary aspects of planning would have to be included for the entire decommissioning procedure. Updated and more complete plans for delayed decontamination activities would be submitted towards the end of the safe storage period and would have to be approved by NRC before the start of the major decontamination activities.

Decommissioning plans must address the following:

1. *Decommissioning alternative.* A description of the alternative to be used for decommissioning must be presented. Plans for processing and disposing of radioactive waste must also be described. Waste disposal plans must assess the availability of waste burial grounds. If waste burial space is unavailable, then contingency plans must be presented that address use of available temporary above-ground waste storage or some other method. Depending on a variety of circumstances, temporary above-ground waste storage may be accomplished offsite or onsite and may require Commission review and approval.

2. *Technical and environmental plans.* Controls and limits on procedures and equipment to ensure occupational and public safety and to protect the environment during decommissioning must be proposed by the licensee. As part of this, details of a quality assurance program should also be submitted. Changes to procedures for safeguarding special nuclear material should be included when appropriate.

3. *Terminal radiation survey.* A plan for a final radiation survey must also be presented to ensure that remaining residual radioactivity is within levels permitted for releasing the property for unrestricted use. Unrestricted access to portions of the property may be desirable prior to full decommissioning. A separate termination survey would be necessary for those areas.

4. *Cost estimate.* An updated cost estimate must be included along with a plan to ensure that adequate decommissioning funds are available to carry out the decommissioning operations. This plan would show how any deficit in present funding would be

covered. If delayed decommissioning is proposed, a method for securing the fund would be proposed. Plans for adjusting funds over the storage period are also needed.

For specific licenses under Parts 30, 40, and 70 detailed plans for the completion of decommissioning are only required where decommissioning could significantly increase health and safety impacts over those of normal operation or if the Commission has previously determined a need for such plans and required them by a license condition. These plans would contain essentially the same information as described above for Parts 50 and 72 licenses. For materials licensees, those plans are not required until after inventories of radioactive materials have been disposed of, preliminary decontamination procedures have been carried out, and contamination remaining after these procedures has been assessed. However, it would be advantageous to licensees and the Commission for decommissioning plans to be submitted prior to the end of operational activities, if possible. It is expected that the need for such a plan will in most cases be anticipated and that a reasonably accurate appraisal of what will be necessary can be accomplished prior to the end of operation. It would therefore be possible for the licensee to submit plans early and obtain approval of these plans in time for decommissioning to proceed promptly following the end of operational activities.

No amendments are proposed which specify limitations on occupational or public doses or effluents to the environment. It is considered sufficient that the requirements of Part 20 continue to apply until the license is terminated by the Commission. The proposed planning requirements are considered appropriate means of assuring that the decommissioning will be carried out in accordance with Part 20 and specifically that doses will be kept as low as reasonably achievable.

D. Financial Assurance

In accordance with its responsibilities as defined by the Atomic Energy Act, the primary responsibility of the NRC with respect to decommissioning is to protect the health and safety of the public. An important aspect of this responsibility is to have reasonable assurance that at the time of termination of operations (including premature closure of the nuclear facility) adequate funds are available so that decommissioning can be carried out in a safe and timely manner. Without this assurance, there could be uncertainties concerning the availability of funds at the time of decommissioning. These uncertainties are of two general types. The first is that the financial condition of a particular organization is difficult to predict years into the future when decommissioning is likely to occur. As a result it is possible that there may be priority or competing claims to these assets. The second type of uncertainty is the possibility that the nuclear facility could be forced to shut down prematurely, thus reducing the time for collecting funds.

The availability of funds for post-accident cleanup is related to financial assurance for decommissioning. The costs of post-accident cleanup can be substantially larger than the costs of decommissioning and the availability of funds for accident cleanup can impact a licensee's capability to decommission the facility following the cleanup. Assurance of funds for post-accident cleanup is more properly covered by use of insurance. Post-accident cleanup activities are broader in scope than decommissioning, that is, they can lead ultimately to either reuse or decommissioning. Accordingly, the funding requirments for accident cleanup are not included in the proposed rule but are contained in 10 CFR 50.54(w) which requires that utility licensees for production and utilization facilities obtain insurance to cover decontamination and cleanup costs associated with onsite property damage resulting from an accident. As discussed below, the acceptability of certain of the funding methods allowed in the proposed regulations depends on this accident cleanup insurance requirement. Accident cleanup insurance for other types of licensees is under consideration in a separate action; an advanced notice of proposed rulemaking is being developed.

Mechanisms for Requiring Financial Assurance

As discussed earlier, financial assurance for the decommissioning of major facilities will be provided by implementation of a funding method with a funding level based on expected decommissioning costs. This includes all Parts 50 and 72 licensees, as well as those licensees under Parts 30, 40, and 70 which are expected to have significant decommissioning costs. Electric utility and some material licensees are given the option of providing financial assurance in a prescribed amount or submitting a decommissioning funding plan which contains an estimate based on a facility-specific evaluation. If financial assurance is provided in the prescribed amount, only a certification pertaining to financial assurance is submitted. This approach is proposed in order to minimize the administrative effort of licensees and the Commission of obtaining reasonable financial assurance for decommissioning and is based on the significant data base on decommissioning developed as part of the policy reevaluation.

The specified amounts are chosen to provide sufficient funds to cover decommissioning costs for most of most of the licensees in each category. For power reactors the amount of $100 million (1984 dollars) was chosen based on data in NUREG/CR–0130 and –0672 (References 2 and 3), which analyze the costs of decommissioning PWRs and BWRs, respectively. This figure also takes into account escalation of these costs to 1984 dollars, additional costs of engineering and planning, use of contractors, and variations in local labor rates, in waste transportation costs, and in local power costs. This amount does not account for costs of shipment of spent fuel which are assumed to be part of operational costs or the costs of demolition of nonradioactive structures which is not required for NRC license termination. The use of an inflation rate of twice that indicated by the Consumer Price Index is an approximation obtained by analyzing the rate of escalation of the major cost elements in the PNL data (i.e., waste disposal, labor, energy, and other), over the last several years, and comparing the net increase in decommissioning costs to the general inflation rate as reflected in the Consumer Price Index. This net increase is due primarily to the large increases in the cost of radioactive waste disposal. If decommissioning costs differ significantly in the future from that approximated by this prescribed amount, the regulation may be modified. Additionally, if at any time the licensee determines that this amount is no longer appropriate for a specific reactor, the regulation would allow submittal of a decommissioning funding plan. For research and testing facilities a specific amount is not set due to the large diversity of facility types.

The amounts for materials licensees were chosen based primarily on data in NUREG/CR–1754 (Reference 12) and on licensing experience. Based on estimates in NUREG/CR–1754, a single major processing laboratory would cost in a range approaching $100,000 to decommission. It is expected that the majority of licensees for which a certification of $100,000 is specified would have only one major laboratory or processing area and a very limited potential for site contamination. For those materials licensees for which assurance of $500,000 is specified, it is expected that several laboratories would typically be involved in radioactive material processing or handling. In some cases, a large number of individual rooms or laboratories may be used in connection with licensed activities, however, only a few would require a major decontamination effort such as the example laboratories studied in NUREG/CR-1754. The $50,000 specified for very large sealed sources is based on licensing experience and is the estimated maximum cost to decommission a large pool-type irradiator.

Of course, many factors will affect decommissioning costs. Licensees who can demonstrate that the expected decommissioning costs for their facility are significantly lower than the applicable prescribed amount have the option of doing by submitting a decommissioning funding plan.

An additional means of reducing administrative effort which has been incorporated into the proposed rule is allowing those materials licensees for which a decommissioning funding plan is required to first supply financial assurance for $500,000 and delay submitting the funding plan until application for license renewal is made, at which time the funding plan can be more efficiently reviewed together with the renewal application.

Funding Methods

The wide diversity in types of nuclear facilities necessitates that the NRC allow latitude in the use of funding methods. In analyzing funding methods which would provide reasonable assurance, NRC has developed the following major classification of funding alternatives:

1. *Prepayment.* Cash or other liquid assets that will retain their value for the projected operating life of the nuclear facility are deposited prior to startup into an account segregated from licensee assets and outside its administrative control. Periodic review and adjustment of the fund is necessary to assure the adequacy of the fund. Prepayment can be in the form of a trust, certificate of deposit, government security, escrow account, or government fund.

2. *External sinking funds.* The external sinking fund requires that a prescribed amount of funds be set aside in an account at fixed intervals over the life of the facility, such that the funds plus accumulated interest would be sufficient to pay for decommissioning costs at the time termination of operation is anticipated. The account would be segregated from licensee assets and outside licensee control. Types of accounts could be similar to those described above for prepayment.

3. *Internal reserve.* This approach usually uses negative net salvage value depreciation that allows estimated decommissioning costs to be accumulated over the life of the nuclear facility. In this method, the funds are not segregated from the company's assets, rather they are invested in its assets. At the end of the nuclear facility's life, bonds are issued against these assets and the funds raised are used to pay for decommissioning. This approach can also take the form of a segregated internal reserve, which is similar to an external sinking fund, except that funds are held by the company.

4. *Insurance, surety bonds, letters of credit, and lines of credit and other guarantee methods.* Insurance could be used to provide coverage for premature decommissioning expenses. An insurance-type mechanism might also be used for all decommissioning expenses, including those planned under normal circumstances. The surety bond, credit methods, and other guarantee methods assures that decommissioning costs will be paid should the licensee default. The licensee would still be responsible to pay for decommissioning. With respect to power reactors, it appears questionable that bonds of the size necessary and for the time involved will be available. However, surety bonds or credit methods appear to be available for nuclear facilities that involve smaller costs and shorter time periods. Contractual arrangements must provide that NCR be notified prior to cancellation, must ensure that a surety bond or credit method remains in effect until the license is terminated, and must be set up such that the beneficiary would be a trustee acceptable to the Commission.

The types of surety arrangements being considered in this proposed rule are similar to those contained in the Commission's recently enacted requirements in 10 CFR part 61. The Commission found in developing those requirements that self insurance for a private sector applicant or licensee would not be an acceptable form of surety.

Another potential funding method of this type is for a licensee, where practical, to obtain a guarantee that the local, state, or Federal government will assume financial responsibility for decommissioning the facility. This would most likely be possible when the licensee is a local, State, or Federal agency or a state-affiliated organization, such as a university or hospital.

Criteria for Funding Methods

The NRC staff considers two primary criteria in evaluating funding methods. These criteria are the degree of assurance of the availability of funds and the cost of providing assurance.

The degree of assurance is a measure of how effective the funding method is in providing assurance that funds for decommissioning will be available when needed. From the Commission's perspective, assurance is the most important criterion.

Prepayment provides the greatest assurance that funds will actually be available for either normal or premature decommissioning since the necessary funds are deposited at startup. Some adjustment will likely be necessary over the period of licensing because of uncertainties in cost estimates and changes in inflation and interest rates.

The insurance alternative also provides excellent assurance in that it could provide coverage for premature decommissioning costs and for licensee default. For electric utility licensees, the property damage insurance required by 10 CFR 50.54(w) provides reasonable assurance of funds for the potentially large costs of decontamination leading up to premature decommissioning. In some instances, such as in the case of government licensees, guarantees of financial responsibility by the appropriate local, State, or Federal government entities are considered adequate in providing assurance. As discussed above, self-insurance is not considered adequate.

Surety methods (for example, surety bonds, lines of credit, letters of credit, secured interests, or other guarantees) can provide adequate assurance to cover default for those licensees to whom they are available. However, from the standpoint of acceptability, sureties have certain disadvantages that must be considered. In particular, contractual arrangements will have to be written such that the surety bond or credit mechanism cannot be terminated by the surety company or bank prior to other arrangements being made, that a surety bond or credit mechanism remains in effect until the license is terminated, and that the surety company itself is financially stable.

The external sinking fund option provides a good level of assurance. Because the external sinking fund is held outside the licensee's assets and control, it would not be vulnerable under most likely trust arrangements if the licensee went bankrupt. On the other hand, in the event of premature decommissioning, there would be a greater likelihood than with the prepayment method that insufficient funds had been accumulated. This situation would be mitigated if the fund was either structured so that higher payments were made earlier in a facility's life, or coupled with a deposit or insurance or surety.

Providing lesser assurance is the internal reserve. Under normal circumstances, the internal reserve would be similar to the external sinking fund in the pattern of funds set aside and should provide adequate funds if a nuclear facility is decommissioned at the end of its expected life. However, because it depends on financing internal to the licensee, the internal reserve is vulnerable to events or situations that undermine the financial solvency of a licensee. A bankrupt or financially troubled licensee would have difficulty in raising capital against its decommissioning reserve and even a segregated internal reserve fund may not be available to pay for decommissioning costs. Thus, the internal reserve is acceptable only if supplemented by a mechanism providing additional assurance such as insurance or surety arrangement.

For most electric utilities, the insurance required by § 50.54(w) is considered sufficient to allow the use of internal reserve. For other licensees, internal reserve would not provide adequate assurance unless backed up by a surety or insurance covering decommissioning costs. In this case, however, it is the surety or insurance that provides the assurance; although the licensee may use an internal reserve to accumulate funds, only the surety or insurance need be reported to NRC.

Cost of assuring funds is an important consideration from the standpoint that an alternative must be reasonably cost effective in order to be acceptable. Cost of a funding method is defined as the incremental revenue requirements that result from using a particular funding method, other factors being equal. (Administrative costs to the NRC and other regulatory agencies are also included.) Cost is sensitive to even relatively small variations in assumed inflation rates, interest and discount rates, expected facility life, Federal tax policies, depreciation and amortization schedules, and other accounting procedures. Based on these variations, each of the funding alternatives has a fairly wide calculated cost range. Taxation policies can have a significant effect on the cost of funding alternatives.

The internal reserve method tends to be less expensive than external sinking funds or prepayment since a company can normally earn more from its own capital structure than by investing in higher grade commercial securities outside the company. The cost of guarantee methods, such as sureties, letters of credit, or insurance would be in addition to normal decommissioning expense.

Funding methods considered acceptable in providing reasonable levels of assurance may be different for different types of facilities. For example, the situation of a large power reactor, can be significantly different than that for a small research or testing facility. Generally for power reactors, state utility commissions regulate retail rates thus permitting utilities to recover the cost of providing electricity from their customers, the decommissioning costs are higher, and the licensees are required by 10 CFR 50.54(w) to carry insurance for post accident decontamination and cleanup. Even financially troubled utilities have sufficient assets to cover the costs of decommissioning. Among utilities, there are also differences, such as multi-asset versus single-asset utilities (i.e., a utility with a single generating facility) or public versus investor-owned utilities.

Based on the above considerations, this proposed decommissioning rule permits a range of options which are expected to provided reasonable assurance of the availability of funds for decommissioning. The acceptable options are specified in the proposed rule. Planned regulatory guides will provide guidance on how these funding methods will be implemented. These requirements and the planned accompanying guidance are similar to those for 10 CFR Part 61.

Periodic Review

The proposed rule would require that decommissioning funding plans contain provisions for periodic review and adjustment in order to assure that funds will be adequate at the time of decommissioning. Appropriate periods for review and the level of effort necessary will vary for different types of licensees and financial considerations. For many cases, routine adjustments for changes in inflation and interest rates might be done annually by the licensee and could be reported in the annual financial report without the need for NRC approval. A technical review of the information in the preliminary plans or the cost estimate for a funding plan could be done less frequently and submitted to NRC for approval. For the shorter term materials licenses, the renewal process may be sufficient for technical reviews.

Existing Licensees

Particular consideration has been given to the case of existing licensees whose funding methods will need to provide an adequate level of assurance within a shorter time frame. The proposed rule would require that a funding method be proposed within two years following the effective date of this rule for production and utilization facilities and within one year for other licensees for which it is required and established as soon as approved by NRC. For funding methods in which funds would normally be accumulated over the entire life of the facility, larger periodic payments would, of course, be necessary in order to accumulate the total decommissioning costs within the remaining lifetime of the facility. When such methods are not coupled with a surety or other guarantee as is allowed in the case of utilities, adequate assurance should be provided by building up the fund to the level that would have been attained if accumulation of funds had been started at the beginning of facility life. Establishment of these decommissioning funds by use of prepayment or accelerated sinking fund by all existing licensees, within a short time following issuance of this rule could have a significant impact on capital markets. To alleviate this impact, existing licensees with estimated decommissioning costs of 5 million dollars or more would be allowed to accumulate an adequate decommissioning fund, as discussed above, over a reasonable period of time following the initial establishment of the fund. If more than 5 years remain prior to license expiration an acceptable period of time would be 5 years or one-third of the remaining license period, whichever is greater.

Extended Decommissioning Period

When decommissioning is to be carried out over an extended period of time such as with SAFSTOR, the proposed rule would require that the decommissioning fund be in an external account unless assurance is being provided by a surety, insurance, or certification method. In this way, for a facility which is no longer producing revenue, the funds would be protected irrespective of licensee stability. This would be done at the beginning of the storage or surveillance period. Review and adjustment of the funding level must continue over the extended decommissioning period.

Request for Comment

The regulatory approach for assuring funds for decommissioning has been particularly difficult to resolve. The issues of concern are: which funding methods to allow for utilities during operation and during any long term decommissioning, and whether to set a prescribed amount for the level of assurance. Additional information and comments are specifically requested by the Commission on the costs and adequacy or assurance of the various funding methods.

More specifically, Commissioners Asselstine and Bernthal continue to be concerned about the vulnerability of the internal funding mechanism for decommissioning funds, particularly where the funds are used to purchase assets or reduce existing debt. They believe the proposed rule should have included two options for public comment; one option would permit the use of unsegregated internal funding for electric utilities (as the staff recommended) and the other option not permitting the use of unsegregated internal funding. Commissioners Asselstine and Bernthal would like public comments on the need to consider the possibility of insolvency and its impact on the continued availability of decommissioning funds.

PIRG, et al., Petition for Rulemaking, Docket No. PRM-50-22.

On July 5, 1977, as supplemented October 7, 1977, and January 3, 1978, the Public Interest Research Group (PIRG), Arizonans for Safe Energy, Citizens United Against Radioactive Environment, Community Action Research Group, Critical Mass Energy Project, Environmental Action Foundation, Environmental Action, Inc., New Mexico Public Interest Research Group, New York Public Interest Research Group, North Anna Environmental Coalition, Texas Public Interest Research Group, and National Consumer Law Center Energy Project (hereinafter the 'petitioners'), petitioned the Commission to initiate rulemaking to promulgate regulations for nuclear power plant decommissioning which would require plant operators to post bonds, to be held in escrow, to ensure that funds would be available for proper and adequate isolation of radioactive material upon each plant's decommissioning. On June 22, 1979, the Commission published in the **Federal Register** (44 FR 36523) a partial denial of the petitioners' request. In this notice the Commission specifically denied the petitioners' request to immediately initiate rulemaking to implement a specific decommissioning funding plan that would require nuclear power plant operators to post surety bonds to cover decommissioning costs. The Commission granted the petitioners' request to reconsider the adequacy of its regulations on decommissioning. The Commission indicated that other issues and funding alternatives raised by the petitioners would be considered within the context of the NRC decommissioning rulemaking proceedings.

In addition to surety bonds, the petitioners advanced two other options to finance nuclear power reactor decommissioning: (1) Funds in an amount sufficient to pay for projected decommissioning would be set aside in an escrow account before commencing reactor operations, and (2) funds would be accumulated in a sinking fund during the life of the plant supplemented by a surety arrangement as necessary to allow for the risk of a licensed utility going bankrupt before the sinking fund had accumulated sufficient funds. The petitioners indicated that the requirements should apply to existing licensees as well as future licensees. The petitioners also raised the issue of the Commission's jurisdiction to regulate the arrangements for decommissioning. The original petitioners joined by others, submitted comments in response to the **Federal Register** notice (44 FR 36523, June 22, 1979). These comments were received on November 21, 1979. The comments discussed NRC's jurisdiction to promulgate rules mandating specific requirements covering decommissioning costs, the need for NRC to establish a rule requiring its licensees to make specific financial plans to meet decommissioning costs, surety bonds as a supplementary option, and the disadvantage of unfunded alternatives.

The PIRG petition and the petitioners' supplementary comments were considered in the development of this proposed rule. The Commission agrees that its regulations should be amended to require that licensees plan for decommissioning costs when needed. For reasons discussed in the previous section, the Commission does not believe it is necessary, or desirable, to require a specific financial method for collecting decommissioning funds. The proposed amendments would require licensees to submit a cost estimate and a proposed financial method for assuring that funds will be available for decommissioning. A number of acceptable methods are indicated. The Commission will review the licensees' funding methods and evaluate them with respect to the new requirements. A licensee's method for providing decommissioning funds must be acceptable to the Commission. This procedure covers all applicants for operating licenses and existing licensees under Part 50. To the extent that the petitioners would require promulgation of a specific method for financing power reactor decommissioning, the petition is denied. To the extent that the proposed amendments would allow consideration of the petitioners' suggested financing methods, including surety bonds if they are available, the petition is granted. This action would complete NRC consideration of the issues raised in PRM-50-22.

E. Residual Radioactivity Levels

Although residual radioactivity limits are being developed in a separate action, much consideration has been given to this issue as part of the overall reevaluation of decommissioning policy. Although an upper limit in terms of dose is being considered, actual levels attained in any case should be as low as reasonably achievable. Based on the information developed, it is expected that contamination levels considered suitable for release for unrestricted use will not be changed significantly enough to affect cost estimates for decommissioning, nor conclusions of the generic environmental impact statement concerning overall impacts of decommissioning. Whatever criteria are applicable, the survey which verifies that these criteria are met and serves as the primary basis of termination of the license must be carefully designed to provide a high degree of reliability.

F. Environmental Review Requirements

In the course of development of this proposed rule, it became apparent that the requirements for environmental reviews related to decommissioning could be reduced.

Environmental Review Requirements at Licensing

Decommissioning is the inevitable result of having built and operated a nuclear facility. The GEIS and its supporting technical data base assessed all of the costs and environmental impacts occurring at the time of decommissioning. These overall impacts, although dependent on the specific decommissioning procedures, are essentially the result of operation and accordingly should be addressed prior to licensing.

As is the present licensing practice, environmental reports and environmental impact statements which are developed in connection with the licensing of major facilities will include the major environmental impacts expected at decommissioning. The major impacts, of which the wastes needing controlled disposal are the most significant, can be reasonably assessed. At the time a facility is licensed, however, it is impractical to plan in detail what specific procedures will be used at decommissioning since decommissioning will not be carried out until many years later. Thus, at this time, it is also impractical to attempt to develop highly detailed analysis of the environmental impacts of specific decommissioning procedures. Since the GEIS and its supporting data base showed that the costs and environmental impacts at decommissioning are small compared to the total costs and impacts of building and operating a major facility such as a reactor, the availability of more detailed information concerning impacts at decommissioning would not affect the NEPA cost-benefit balance. Thus, no amendment to the regulations is being proposed in regard to the consideration of decommissioning impacts in environmental reviews at licensing.

Environmental Reviews at Decommissioning

At the end of operation, when a facility must be decommissioned, application for termination of license is made and, in the case of major facilities, a detailed decommissioning plan is submitted. As stated above, the overall environmental impacts occuring at decommissioning, of which the radioactive wastes resulting from operation and needing controlled disposal are the most significant, have already been evaluated in environmental impact statements prepared in connection with the issuance of the construction permit and operating license for the facility. In view of these circumstances and on the basis of information in the draft GEIS and its supporting technical data base indicating that the environmental impacts associated with decommissioning are unlikely to be significant, the Commission is of the opinion that there is no need, absent special circumstances, to prepare an environmental impact statement in connection with the issuance of a license amendment or order authorizing the decommissioning of a facility other than a waste disposal facility. In most cases, preparation of an environmental assessment which supplements the previously prepared environment impact statements should be sufficient. The Commission notes, however, that there may be situations in which the special nature of the decommissioning action necessitates the preparation of an environmental impact statement.

This proposed rule has been developed to assure that decommissioning can and will be accomplished in a safe and efficient manner and that the impacts at decommissioning will be minimized to the extent practical. The draft GEIS indicates that for any viable decommissioning alternative, radioactivity released to the environment and associated radiation doeses are substantially less than those associated with operation and maintenance of a reactor during its lifetime and that public doses from decommissioning activities are negligible (calculated in the background documents as roughly a few micro-rem to the maximally exposed individual). Occupational doses during the decommissioning of a reactor are, for the short period of active dismantlement, comparable to that occurring during operation and maintenance, and over the longer period of a safe storage period are much lower.

Since in most instances environmental impacts are unlikely to be significant enough to warrent the development of an environmental impact statement, the rule proposes that the Commission no longer be required to prepare environmental impact statements in connection with the issuance of license amendments or orders authorizing the decommissioning of facilities licensed under Parts 50 and 72. Instead, the Commission would prepare environemental assessments which would supplement environmental impact statements previously prepared in connection with the facility. Although this environmental review procedure is expected to accommodate most decommissioning actions, it should be noted that under the critieria in revised 10 CFR Part 51 an environmental assessment may result in a conclusion that an environmental impact statement is required in the particular circumstances of the proposed Federal decommissioning action. The environmental assessment would be based on information provided by the licensee in a supplement to the environmental report submitted at the decommissioning stage. The information submitted by the licensee would take account of any changes to the estimated environmental impacts based on the information in the decommissioning plan.

The information in the data base and the conclusions of the GEIS will also assist in evaluating decommissioning plans. If unique methods are proposed by a licensee which are significantly different from those studied by the Commission, the Commission retains discretion to require an environmental impact statement in special circumstances.

Categorical Exclusion From Environmental Reviews

The Commission has identified a category of actions connected with the proposed requirements which appears to meet the criterion for categorical exclusion set out in 10 CFR 51.22(a). Presently there are eighteen categories of actions designated as such, thus the following category of actions is designated Category 19:

Category of Actions

19. Approvals of decommissioning funding plans.

Discussion and Finding

Although decommissioning funding plans concern how licensees expect to carry out the activities required to decommission their facilities, the approval of these plans does not authorize a licensee to perform these activities. The principal purpose of considering decommissioning activities at this time is to provide information which will enable the Commission to determine whether the licensee's plan for assuring funds for decommissioning is adequate. Approval of a decommissioning funding plan affects the financial arrangements of the licensee but does not affect the scope and nature of the licensed activity. These actions in and of themselves do not have an environmental impact.

Accordingly, the Commission finds that approvals of decommissioning funding plans (Category 19) comprise a category of actions which do not individually or cumulatively have a significant effect on the human environment, designates Category 19 as a categorical exclusion, and directs that Category 19 be listed in 10 CFR 51.22(c) as a categorical exclusion.

Separate Views of Commissioner Bernthal

I feel compelled to comment on the nature of this rule setting forth, as it does, prescriptive requirements for assuring that financial resources are available for decommissioning of nuclear facilities. My voting record on general financial qualifications reviews reflects my long opposition to what I consider to be inappropriate and ill-suited Commission involvement in financial matters related to the construction and operation of nuclear facilities.

However, there are distinctions between construction and operation of these facilities and their safe decommissioning. First, the Commission already has prescriptive requirements for construction and operation which, independently from financial review requirements, provide assurance that those tasks will be accomplished safely. For decommissioning there are no such independent requirements in the Commission's regulatory scheme. The financial options which the Commission would adopt by these rule changes appear, therefore, to be justifiable as a means to assure that expeditious action can be taken for safe implementation of whatever decommissioning plan is selected by licensees. Second, abandonment of a facility during construction because of financial problems does not create a health and safety problem. Abandonment of a decommissioning plan before completion may well involve health and safety considerations. Finally, apart from financial considerations, applicants have an incentive to comply with regulations governing the construction of nuclear facilities because their receipt of a permit or license for the facility depends upon such compliance. Absent the proposed decommissioning regulations, no such incentive would exist to dedicate funds in advance for successful completion of decommissioning.

For these reasons, I believe the proposed regulations provide a necessary adjunct to the Commission's authority to take reasonable steps for the protection of public health and safety in the decommissioning of nuclear facilities.

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Note.—Free single copies of reference items 14 and 20, to the extent of supply, may be requested by writing to the Publication Services Section, Division of Technical Information and Document Control, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

Copies of all other reference documents may be purchased by calling (301) 492–9530 or writing to the Publication Services Section, Division of Technical Information and Document Control, U.S. Nuclear Regulatory Commission, Washington, DC 20555, or purchased from the National Technical Information Service, Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161.

Environmental Impace Statement: Availability

As required by the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in 10 CFR Part 51, the NRC has prepared a draft environmental impact statement on the decommissioning of nuclear facilities.

This draft environmental impact statement is available for inspection and copying for a fee in the NRC Public Document Room, 1717 H Street NW., Washington, DC. Single copies of the draft environmental impact statement may be obtained from Carl Feldman, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301)443–7910.

Paperwork Reduction Act Statement

This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). This rule has been submitted to the Office of Management and Budget for review and approval of the paperwork requirements.

Regulatory Analysis

The Commission has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. The draft analysis is available for inspection and copying for a fee in the NRC Public Document Room, 1717 H Street NW., Washington, DC. Single copies of the analysis may be obtained from C.R. Mattsen, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 443-7910.

The Commission requests public comments on the draft regulatory analysis. Comments on the draft analysis may be submitted to the NRC as indicated under the ADDRESSES heading.

Regulatory Flexibility Analysis

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the NRC has carefully considered the effect on small entities in developing the proposed rule and has attempted to tier the requirements to reduce the impact on small entities to the extent possible while adequately protecting health and safety.

Based on the information presently available, it is not expected that this proposed rule, if promulgated, will have a significant economic impact on a substantial number of small entities. Although the impact may be considered significant to some, for the large majority of small entities, it is expected to be minimal.

The proposed rulemaking would broadly affect all Commission applicants and licensees and, because Agreement States will be required to maintain compatibility with the proposed changes, the proposed rule would also affect Agreement State applicants and licensees. There are approximately 9,000 Commission licenses, which include about 5,200 byproduct material licenses under Parts 30 through 34, 2,500 medical licenses under Part 35, 400 source material licenses under Part 40, 200 production and utilization licenses (including approximately 50 applications in various stages of review) under Part 50, 700 special nuclear material licenses under Part 70, and 1 license and approximately 5 potential applicants under Part 72. Between 11,000 and 12,000 Agreements States' licensees would also be affected.

The Commission estimates that approximately 43 percent of its licensees would be considered small entities under the criteria set out in the size standards by the Small Business Administration in 13 CFR Part 121 (e.g., for most licensees less than 500 employees, for hospitals less than 150 beds, and for other medical licensees less than $1.5 million annual gross receipts). Licensees under 10 CFR Parts 50 and 72 would not be considered small entities.

All licensees including small entities will be required to keep records important to decommissioning. In general, for small licensees, such recordkeeping is "good practice" and should not constitute a significant change in operation. Generally, keeping records important to decommissioning reduces both the costs and health and safety impacts of decommissioning and can also result in savings in doses or costs during operation. Costs of recordkeeping would tend to be recouped either in operation or at decommissioning.

The changes proposed in this rule at the time of termination of license will affect few small entities. These changes consist primarily of specifying in more detail contents of decommissioning plans, presently called "decontamination plans." Although more detailed plans may be required than have been considered acceptable in the past, there will also be a reduction in administrative effort because there will be less uncertainty as to what is expected. Overall, these changes are not expected to have a significant impact.

The most significant impact of this rule on licensees is likely to result from the financial assurance requirements. A cost estimate for decommissioning and a method of providing assurance of funds for decommissioning will be required of roughly 830 Commission licensees of which few if any will be small entities. Roughly another 660 Commission licensees including about 280 small entities will have the option of providing financial assurance in a prescribed amount and submitting a certification to that effect or submitting a funding plan to support a lower amount. A similar number of Agreement State licensees would also be affected. Those small entities affected would be almost exclusively industrial licensees. Because the historical information indicates that such small industrial licensees are the most likely to default, it is particularly important that financial assurance be provided by these licensees. The rule allows as much flexibility as possible to licensees for providing financial assurance, in order to reduce the impact. Also, the economic impact of making cost estimates can be reduced by using the data base which has been developed.

The cost of this requirement depends on the method used. A surety or insurance method is likely to be used by small entities; it is estimated to cost approximately 1 to 2% of the face value, or 1 to 2% of decommissioning costs annually, plus the administrative cost of either developing a cost estimate and reporting on the funding methods to NRC or of making a certification. The cost of a surety using the prescribed amounts proposed in the rule would thus be in the range of $500–$10,000 per year. For a few small entities affected this would be a significant economic impact, however, these cases would present the highest risk of default.

A more detailed analysis of impacts to small entities is included in the Regulatory Analysis.

Because of the widely differing conditions under which the licensees covered by this proposed regulation operate, the Commission is particularly seeking comment from small entities as to how the regulations will affect them and how the regulations may be tiered or otherwise modified to impose less stringent requirements on small entities while still adequately protecting the public health and safety. Those small entities which offer comments on how the regulations could be modified to take into account the differing needs of small entities should specifically discuss the following items:

(a) The size of their business and how the proposed regulations would result in a significant economic burden upon them as compared to larger organizations in the same business community.

(b) How the proposed regulations could be modified to take into account their differing needs or capabilities.

(c) The benefits that would accrue, or the detriments that would be avoided, if the proposed regulations were modified as suggested by the commenter.

(d) How the proposed regulations, as modified, would more closely equalize the impact of NRC regulations or create more equal access to the benefits of Federal programs as opposed to providing special advantages to any individuals or groups.

(e) How the proposed regulations, as modified, would still adequately protect the public health and safety.

The comments should be sent to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

List of Subjects

10 CFR Part 30

Byproduct material, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Penalty, Radiation Protection, Reporting and recordkeeping requirements.

10 CFR Part 40

Government contracts, Hazardous materials—transportation, Nuclear materials, Penalty, Reporting and recordkeeping requirements, Source material, Uranium.

10 CFR Part 50

Antitrust, Classified information, Fire prevention, Incorporation by reference, Intergovernmental relations, Nuclear power plants and reactors, Penalty, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements.

10 CFR Part 51

Administrative practice and procedure, Environmental impact statement, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements.

10 CFR Part 70

Hazardous materials—transportation, Nuclear materials, Packaging and containers, Penalty, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Security measures, Special Nuclear material.

10 CFR Part 72

Manpower training programs, Nuclear materials, Occupational safety and health, Reporting and recordkeeping requirements, Security measures, Spent fuel.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is proposing to adopt the following amendments to 10 CFR Parts, 30, 40, 50, 51, 70, and 72.

PART 30—RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

1. The authority citation for Part 30 is revised to read as follows:

Authority: Secs. 81, 82, 161, 182, 183, 186, 68 Stat. 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2111, 2112, 2201, 2232, 2233, 2236, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

Section 30.7 also issued under Pub. L. 95–601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 30.34(b) also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 30.61 also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273), §§ 30.3, 30.34(b) and (c), 30.41(a) and (c), and 30.53 are issued under sec. 161b, 68 Stat. 948 as amended (42 U.S.C. 2201(b)); and §§ 30.36, 30.51, 30.52, and 30.55 are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

2. Section 30.4 is amended by adding a new paragraph (y) to read as follows:

§ 30.4 Definitions.

* * * * *

(y) "Decommission" means to remove (as a facility) safely from service and reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of license.

3. Section 30.32 is amended by adding a new paragraph (g) to read as follows:

§ 30.32 Application for specific licenses.

* * * * *

(g) As provided by § 30.35, certain applications for specific licenses filed under this part and Parts 32 through 35 of this chapter must contain a proposed decommissioning funding plan or a certification of financial assurance for decommissioning. In the case of renewal applications submitted before [insert a date one year after the effective date of the final rule] this submittal may follow the renewal application but must be submitted on or before [insert a date one year after the effective date of the final rule].

4. Section 30.33 is amended by deleting the word "and" following paragraph (a)(4), replacing the period following paragraph (a)(5) with a semicolon, adding the word "and" following paragraph (a)(5), and adding a new paragraph (a)(6) to read as follows:

§ 30.33 General requirements for issuance of specific licenses.

(a) An application for a specific license will be approved if:

* * * * *

(6) The applicant's proposed decommissioning funding plan or certification of financial assurance for decommissioning, if required by § 30.35(a) or (b), includes sufficient information to demonstrate that the proposed funding method will provide reasonable assurance that funds will be available to decommission the facility in a safe and timely manner.

* * * * *

5. Section 30.34 is amended by adding new paragraphs (h) and (i) to read as follows:

§ 30.34 Terms and conditions of licenses.

* * * * *

(h)(1) Each holder of a specific license issued on or after [insert a date 1 year after the effective date of the final rule] which is of a type described in § 30.35(a) or (b), shall provide financial assurance for decommissioning in accordance with the criteria set forth in § 30.35.

(2) On or before [insert a date one year after the effective date of the final rule], each holder of a specific license of a type described in § 30.35(a) shall submit a decommissioning funding plan or a certification of financial assurance for decommissioning in an amount at least equal to $500,000 in accordance with the criteria set forth in § 30.35. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan at this time, the licensee shall include a decommissioning funding plan in any application for license renewal.

(3) On or before [insert a date 1 year after the effective date of the final rule], each holder of a specific license of a type described in § 30.35(b) shall submit a certification of financial assurance for decommissioning or a decommissioning funding plan in accordance with the criteria set forth in § 30.35.

(4) As of [insert a date 1 year after the effective date of the final rule], each licensee covered by § 30.35(a) or (b) shall provide financial assurance for decommissioning as a condition of license. If a decommissioning funding plan has been submitted to the Commission, implementing the plan becomes a condition of the license upon approval of the plan.

(i) Each person licensed under this part or Parts 32 through 35 of this chapter shall keep records of information important to the safe and effective decommissioning of the facility in a file explicitly for this purpose until the license is terminated by the Commission. If records of relevant information are kept for other purposes, reference to these records and their locations may be substituted. Information the Commission considers important to decommissioning consists of—

(1) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when significant contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must

include any known information on identification of involved nuclides, quantities, forms, and concentrations.

(2) As-built drawings and modifications of structures and equipment in high radiation areas and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

6. A new § 30.35 is added to read as follows:

§ 30.35 Financial assurance for decommissioning.

(a) Each applicant for a specific license authorizing the possession and use of unsealed byproduct material of half-life greater than 120 days and in quantities exceeding 10^5 times the applicable quantities set forth in Appendix C of Part 20 shall submit a decommissioning funding plan as described in paragraph (d) of this section. Each holder of such a license shall provide financial assurance for decommissioning; required submittals for providing financial assurance are set out in § 30.34(h)(2).

(b) Each applicant for or holder of a specific license authorizing possession and use of by product material of half-life greater than 120 days and in quantities specified in paragraph (c) of this section shall either—

(1) Submit a decommissioning funding plan as described in paragraph (d) of this section; or

(2) Submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by paragraph (c) of this section using one of the methods described in paragraph (e) of this section. For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but prior to the receipt of licensed material.

(c) Table of required amounts of financial assurance for decommissioning by quantity of material.

Greater than 10^4 but less than or equal to 10^5 times the applicable quantities of Appendix C of Part 20 in unsealed form	$500,000
Greater than 10^3 but less than or equal to 10^4 times the applicable quantities of Appendix C of Part 20 in unsealed form	100,000
Greater than 10^{10} times the applicable quantities of Appendix C of Part 20 in sealed sources	50,000

(d) Each decommissioning funding plan must contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning including means of adjusting cost estimates and associated funding levels over the life of the facility.

(e) Financial assurance for decommissioning must be provided by one or more of the following methods:

(1) *Prepayment.* Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets that will retain their value over the projected operating life of the facility and that are in an amount such that the principal plus accumulated earnings would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

(2) *A surety method or insurance.* A surety method or insurance is a guarantee that decommissioning costs will be paid should the licensee default. A surety method may be in the form of a surety bond, letter of credit, line of credit, secured interest, or other guarantee method. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

(i) The surety or insurance must be open-ended or, if written for a specified term, such as five years, must be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the Commission, the beneficiary, and the licensee of its intention not to renew. The surety or insurance must also provide that the beneficiary may automatically collect prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the Commission within 30 days after receipt of notification of cancellation.

(ii) The beneficiary of the surety or insurance must be a trustee acceptable to the Commission such as an appropriate state or Federal government agency or a major financial organization.

(iii) The surety or insurance must remain in effect until the Commission has terminated the license.

(3) An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by the periodic deposit of a prescribed amount into an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of the periodic deposits plus accumulated earnings would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

(4) In the case of Federal, State, or local government licensees, a certification that the appropriate government entity will be guarantor of decommissioning funds.

(5) Other funding methods which are demonstrated by the applicant or licensee to provide comparable assurance to methods listed in paragraphs (c) (1) through (3) of this section.

7. Section 30.36 is revised to read as follows:

§ 30.36 Expiration and termination of licenses.

(a) Except as provided in § 30.37(b) and paragraph (e) of this section, each specific license expires at the end of the day, in the month and year stated in the license.

(b) Each licensee shall notify the Commission promptly, in writing under § 30.6, and request termination of the license when the licensee decides to terminate all activities involving materials authorized under the license. This notification and request for termination of the license must include the reports and information specified in paragraphs (c)(1) (iv) and (v) of this section and a plan for completion of decommissioning if required by paragraph (c)(2) of this section or by license condition.

(c)(1) If a licensee does not submit an application for licensee renewal under § 30.37, the license shall on or before the expiration date specified in the license—

(i) Terminate use of byproduct material;

(ii) Remove radioactive contamination to the extent practicable except for those procedures covered by paragraph (c)(2)(i) of this section;

(iii) Properly dispose of byproduct material;

(iv) Submit a completed form NRC-314, which certifies information concerning the disposition of materials; and

(v) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates that the premises are suitable for release for unrestricted use in some other manner. The licensee shall, as appropriate—

(A) Report levels of radiation in units of microrads per hour of beta and gamma radiation at one centimeter and gamma radiation at one meter from surfaces, and report levels of radioactivity in units of disintegrations per minute (or microcuries) per 100 square centimeters removable and fixed for surfaces, microcuries per milliliter for water, and picocuries per gram for solids such as soils or concrete; and

(B) Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

(2)(i) In addition to the information required under paragraphs (c)(1) (iv) and (v) of this section, the licensee shall submit a plan for completion of decommissioning if the procedures necessary to carry out decommissioning have not been previously approved by the NRC, are extensive, and could significantly increase potential health and safety impacts to workers or to the public such as in cases where—

(A) Workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation; or

(B) Procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

(C) Procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation; or

(D) Procedures would involve techniques not applied routinely during maintenance operations.

(ii) Procedures with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

(iii) The proposed decommissioning plan, if required by paragraph (c)(2)(i) of this section or by license condition, must include—

(A) Discussion of planned decommissioning activities;

(B) Description of methods used to assure protection of workers and the environment against radiation hazards during decommissioning;

(C) A description of the planned final radiation survey; and

(D) An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and plan for assuring the availability of adequate funds for completion of decommissioning.

(iv) The proposed decommissioning plan will be approved by the Commission if the information therein demonstrates that the decommissioning will be completed as soon as is reasonable and that the health and safety of workers and the public will be adequately protected.

(3) Upon approval of the decommissioning plan by the Commission, the licensee shall complete decommissioning in accordance with the approved plan. As a final step in decommissioning, the licensee shall again submit the information required in paragraph (c)(1)(v) of this section and shall certify the disposition of accumulated wastes for decommissioning.

(d) If the information submitted under paragraphs (c)(1)(v) or (c)(3) of this section does not adequately demonstrate that the premises are suitable for release for unrestricted use, the Commission will inform the licensee of the appropriate further actions required for termination of license.

(e) Each specific license continues in effect beyond the expiration date if necessary with respect to possession of residual byproduct material present as contamination until the Commission notifies the licensee in writing that the license is terminated. During this time, the licensee shall—

(1) Limit actions involving byproduct material to those related to decommissioning; and

(2) Continue to control entry to restricted areas until they are suitable for release for unrestricted use and the Commission notifies the licensee in writing that the license is terminated.

(f) Specific licenses will be terminated by written notice to the licensee when the Commission determines that—

(1) Byproduct material has been properly disposed;

(2) Reasonable effort has been made to the eliminate residual radioactive contamination, if present; and

(3)(i) A radiation survey has been performed which demonstrates that the premises are suitable for release for unrestricted use; or

(ii) Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release for unrestricted use.

PART 40—DOMESTIC LICENSING OF SOURCE MATERIAL

8. The authority citation for Part 40 continues to read as follows:

Authority: Secs. 62, 63, 64, 65, 81, 161, 182, 183, 186, 68 Stat. 932, 933, 935, 948, 953, 954, 955, as amended, secs. 11e(2), 83, 84, Pub. L. 95–604, 92 Stat. 3033, as amended, 3039, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2014(e)(2), 2092, 2093, 2094, 2095, 2111, 2113, 2114, 2201, 2232, 2233, 2236, 2282); secs. 274, Pub. L. 86–373, 73 Stat. 688 (42 U.S.C. 2021); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246, (42 U.S.C. 5841, 5842, 5846).

Section 40.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 40.31 (g) also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 40.46 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 40.71 also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 40.3, 40.25(d)(1)–(3), 40.35(a)–(d), 40.41 (b) and (c), 40.46, 40.51 (a) and (c), and 40.63 are issued under sec. 161b, 68 Stat. 948, as amended, (42 U.S.C. 2201(b)); and §§ 40.25 (c) and (d) (3) and (4), 40.26(c)(2), 40.35(e), 40.42, 40.61, 40.62, 40.64 and 40.65 are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

9. Section 40.4 is amended by adding a new paragraph (r) to read as follows:

§ 40.4 Definitions.

* * * * *

(r) "Decommission" means to remove (as a facility) safely from service and reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of license.

10. Section 40.31 is amended by adding a new paragraph (i) to read as follows:

§ 40.31 Applications for specific licenses.

* * * * *

(i) As provided by § 40.36, certain applications for specific licenses filed under this part must contain a proposed decommissioning funding plan or a certification of financial assurance for decommissioning. In the case of renewal applications submitted before [insert a date one year after the effective date of the final rule] this submittal may follow the renewal application but must be submitted on or before [insert a date one year after the effective date of the final rule].

11. Section 40.32 is amended by adding a new paragraph (g) to read as follows:

§ 40.32 General requirements for issuance of specific licenses.

An application for a specific license will be approved if:

* * * * *

(g) The applicant's proposed decommissioning funding plan or certification of financial assurance for decommissioning, if required by § 40.36 (a) or (b), includes sufficient information to demonstrate that the proposed funding method will provide reasonable assurance that funds will be available to decommission the facility in a safe and timely manner.

12. A new § 40.36 is added to read as follows:

§ 40.36 Financial assurance for decommissioning.

Except for licenses authorizing the receipt, possession, and use of source material for uranium or thorium milling, or byproduct material at sites formerly associated with such milling, for which financial assurance requirements are set forth in Appendix A of this part, criteria for providing financial assurance for decommissioning are as follows:

(a) Each applicant for a specific license authorizing the possession and use of more than 100 mCi of source material in a readily dispersible form shall submit a decommissioning funding plan. Each holder of such a license shall provide financial assurance for decommissioning; required submittals for providing financial assurance are set out in § 40.41(f)(2).

(b) Each applicant for or holder of a specific license authorizing possession and use of quantities of source material greater than 10 mCi but less than or equal to 100 mCi in a readily dispersible form shall either—

(1) Submit a decommissioning funding plan as described in paragraph (c) of this section; or

(2) Submit a certification that financial assurance for decommissioning has been provided in the amount of $100,000 using one of the methods described in paragraph (d) of this section. For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but prior to the receipt of licensed material.

(c) Each decommissioning funding plan must contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning including means of adjusting cost estimates and associated funding levels over the life of the facility.

(d) Financial assurance for decommissioning must be provided by one or more of the following methods:

(1) *Prepayment.* Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets that will retain their value over the projected operating life of the facility and that are in amount such that the principal plus accumulated earnings would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

(2) *A surety method or insurance.* A surety method or insurance is a guarantee that decommissioning costs will be paid should the licensee default. A surety method may be in the form of a surety bond, letter of credit, line of credit, secured interest, or other guarantee method. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

(i) The surety or insurance must be open-ended or, if written for a specified term, such as five years, must be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the Commission, the beneficiary, and the licensee of its intention not to renew. The surety or insurance must also provide that the beneficiary may automatically collect prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the Commission within 30 days after receipt of notification of cancellation.

(ii) The beneficiary of the surety or insurance must be a trustee acceptable to the Commission such as an appropriate state or federal government agency or a major financial organization.

(iii) The surety or insurance must remain in effect until the Commission has terminated the license.

(3) An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by the periodic deposit of a prescribed amount into an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of the periodic deposits plus accumulated earnings would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

(4) In the case of Federal, State, or local government licensees, a certification that the appropriate government entity will be guarantor of decommissioning funds.

(5) Other funding methods which are demonstrated by the applicant or licensee to provide comparable assurance to methods listed in paragraphs (c) (1) through (3) of this section.

13. Section 40.41 is amended by adding new paragraphs (f) and (g) to read as follows:

§ 40.41 Terms and conditions of licenses.

* * * * *

(f)(1) Each holder of a specific license issued on or after [insert a date 1 year after the effective date of the final rule] which is covered by § 40.36 (a) or (b), shall provide financial assurance for decommissioning in accordance with the criteria set forth in § 40.36.

(2) On or before [insert a date one year after the effective date of the final rule], each holder of a specific license covered by § 40.36(a) shall submit a decommissioning funding plan or certification of financial assurance for decommissioning in an amount at least equal to $500,000 in accordance with the criteria set forth in § 40.36. If the licensee submits the certification of financial assurance rather than a decommissioning funding plea at this time, the licensee shall include a decommissioning funding plan in any application for license renewal.

(3) On or before [insert a date 1 year after the effective date of the final rule], each holder of a specific license covered by § 40.36(b) shall submit a certification of financial assurance for decommissioning or a decommissioning funding plan in accordance with the criteria set forth in § 40.36.

(4) As of [insert date 1 year after the effective date of the final rule], each licensee covered by § 40.36 (a) or (b) shall provide financial assurance for decommissioning as a condition of license. If a decommissioning funding plan has been submitted to the Commission, implementing the plan becomes a condition of the license upon approval of the plan.

(g) Each person licensed under this part shall keep records of information important to the safe and effective decommissioning of the facility in a file explicitly for this purpose until the license is terminated by the Commission. If records of relevant information are kept for other purposes, reference to these records and their locations may be substituted. Information the Commission considers important to decommissioning consists of—

(1) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when significant contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information on

identification of involved nuclides, quantities, forms, and concentrations.

(2) As-built drawings and modifications of structures and equipment in high radiation areas and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

14. Section 40.42 is revised to read as follows:

§40.42 Expiration and termination of licenses.

(a) Except as provided in § 40.43(b) and paragraph (e) of this section, each specific license expires at the end of the day, in the month and year stated in the license.

(b) Each licensee shall notify the Commission promptly, in writing under § 40.5, and request termination of the license when the licensee decides to terminate all activities involving materials authorized under the license. This notification and request for termination of the license must include the reports and information specified in paragraphs (c)(1) (iv) and (v) of this section and a plan for completion of decommissioning, if required by paragraph (c)(2) of this section or by license condition.

(c)(1) If a licensee does not submit an application for license renewal under § 40.43, the licensee shall on or before the expiration date specified in the license—

(i) Terminate use of source material;

(ii) Remove radioactive contamination to the extent practicable except for those procedures covered by paragraph (c)(2)(i) of this section;

(iii) Properly dispose of source material;

(iv) Submit a completed form NRC-314, which certifies information concerning the disposition of materials; and

(v) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demostrates that the premises are suitable for release for unrestricted use in some other manner. The licensee shall, as appropriate—

(A) Report levels of radiation in units of microrads per hour of beta and gamma radiation at one centimeter and gamma radiation at one meter from surfaces, and report levels of radioactivity in units of disintegrations per minute (or microcuries) per 100 square centimeters removable and fixed for surfaces, microcuries per milliliter for water, and picocuries per gram for solids such as soils or concrete; and

(B) Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

(2)(i) In addition to the information required under paragraphs (c)(1) (iv) and (v) of this section, the licensee shall submit a plan for completion of decommissioning if the procedures necessary to carry out decommissioning have not been previously approved by the NRC, are extensive, and could significantly increase potential health and safety impacts to workers or to the public such as in cases where—

(A) Workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation; or

(B) Procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

(C) Procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation; or

(D) Procedures would involve techniques not applied routinely during maintenance operations.

(ii) Procedures with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

(iii) The proposed decommissioning plan, if required by paragraph (c)(2)(i) of this section or by license condition, must include—

(A) Discussion of planned decommissioning activities;

(B) Description of methods used to assure protection of workers and the environment against radiation hazards during decommissioning;

(C) A description of the planned final radiation survey; and

(D) An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and plan for assuring the availability of adequate funds for completion of decommissioning.

(iv) The proposed decommissioning plan will be approved by the Commission if the information therein demonstrates that the decommissioning will be completed as soon as is reasonable and that the health and safety of workers and the public will be adequately protected.

(3) Upon approval of the decommissioning plan by the Commission, the licensee shall complete decommissioning in accordance with the approved plan. As a final step in decommissioning, the licensee shall again submit the information required in paragraph (c)(1)(v) of this section and shall certify the disposition of accumulated wastes from decommissioning.

(d) If the information submitted under paragraphs (c)(1)(v) or (c)(3) of this section does not adequately demonstrate that the premises are suitable for release for unrestricted use, the Commission will inform the licensee of the appropriate further actions required for termination of license.

(e) Each specific license continues in effect beyond the expiration date if necessary with respect to possession of residual source material present as contamination until the Commission notifies the licensee in writing that the license is terminated. During this time, the licensee shall—

(1) Limit actions involving source material to those related to decommissioning; and

(2) Continue to control entry to restricted areas until they are suitable for release for unrestricted use and the Commission notifies the licensee in writing that the license is terminated.

(f) Specific licenses will be terminated by written notice to the licensee when the Commission determines that—

(1) Source material has been properly disposed;

(2) Reasonable effort has been made to eliminate residual radioactive contamination, if present; and

(3)(i) A radiation survey has been performed which demonstrates that the premises are suitable for release for unrestricted use; or

(ii) Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release for unrestricted use.

PART 50—DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

15. The authority citation for Part 50 continues to read as follows:

Authority: Secs. 103, 104, 161, 182, 183, 186, 189, 68 Stat. 936, 937, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 1244, as amended (42 U.S.C. 2133, 2134, 2201, 2232, 2233, 2236, 2239, 2282); secs. 201, 202, 206, 88 Stat. 1242, 1244, 1246, as amended (42 U.S.C. 5841, 5842, 5846), unless otherwise noted.

Section 50.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 50.57(d), 50.58, 50.91, and 50.92 also issued under Pub. L. 97-415, 96 Stat. 2071, 2073 (42 U.S.C. 2133, 2139). Section 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Sections 50.80–50.81 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C.

2234). Sections 50.100–50.102 also issued under sec. 186, 68 Stat. 955 (42 U.S.C. 2236).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273), §§ 50.10 (a), (b), and (c), 50.44, 50.46, 50.48, 50.54, and 50.80(a) are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); §§ 50.10 (b) and (c) and 50.54 are issued under sec. 161i, 68 Stat. 949, as amended (42 U.S.C. 2201(i)); and §§ 50.55(e), 50.59(b), 50.70, 50.71, 50.72, 50.73, and 50.78 are issued uder sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

16. Section 50.2 is amended by adding a new paragraph (y) to read as follows:

§ 50.2 Definitions.

* * * * *

(y) "Decommission" means to remove (as a facility) safely from service and reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of license.

17. Section 50.33 is amended by revising paragraphs (f) (2) and (4) and adding paragraph (k) to read as follows:

§ 50.33 Contents of applications; general information.

Each application shall state:

* * * * *

(f) Except for an electric utility applicant for a license to operate a utilization facility of the type described in § 50.21(b) or § 50.22, information sufficient to demonstrate to the Commission the financial qualification of the applicant to carry out, in accordance with regulations in this chapter, the activities for which the permit or license is sought. As applicable, the following should be provided:

* * * * *

(2) If the application is for an operating license, the applicant shall submit information that demonstrates the applicant possesses or has reasonable assurance of obtaining the funds necessary to cover estimated operation costs for the period of the license, plus the estimated costs of decommissioning the facility. The applicant shall submit estimates for total annual operating costs for each of the first five years of operation of the facility and estimates of the costs to decommission the facility. The applicant shall also indicate the source(s) of funds to cover these costs. An application to renew or extend the term of an operating license must include the same financial information as is required in an application for an initial license.

* * * * *

(4) The Commission may request an established entity or newly-formed entity to submit additional or more detailed information respecting its financial arrangements and status of funds if the Commission considers this information appropriate. This may include information regarding a licensee's ability to continue the conduct of the activities authorized by the license and to decommission the facility.

* * * * *

(k)(1) For an application for an operating license for a production or utilization facility, information on how reasonable assurance will be provided that funds will be available to decommission the facility. Except in the case of an electric utility, this information must consist of a proposed decommissioning funding plan. An electric utility may submit either a proposed decommissioning funding plan or a certification that financial assurance for decommissioning will be provided in an amount at least equal to $100,000,000 (1984 dollars) adjusted annually for inflation using an inflation rate twice that indicated by the change in the Consumer Price Index published by the U.S. Department of Labor, Bureau of Labor Statistics. This certification must also show that the financial assurance will be provided by a means acceptable to the Commission as specified in paragraphs (k) (2) and (4) of this section. A decommissioning funding plan must contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning including means of adjusting cost estimates and associated funding levels over the life of the facility.

(2) As provided in paragraphs (k) (3) and (4) of this section, financial assurance may be provided by the following methods:

(i) *Prepayment.* Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets that will retain their value over the projected operating life of the facility and that are in such amount that the principal plus accumulated earnings would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

(ii) *External sinking fund.* An external sinking fund is a fund established and maintained by the periodic deposit of a prescribed amount into an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of the periodic deposits plus accumulated earnings would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate or deposit of government securities.

(iii) A surety method or insurance. A surety method or insurance is a guarantee that decommissioning costs will be paid should the licensee default. A surety method may be in the form of a surety bond, letter of credit, line of credit, secured interest, or other guarantee method. Any surety method or insurance used to provide financial insurance for decommissioning must contain the following conditions.

(A) The surety or insurance must be open-ended or, if written for a specified term, such as five years, must be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the Commission, the beneficiary, who must be a Commission-approved trustee, and the licensee of its intention not to renew. The surety or insurance must also provide that the beneficiary may automatically collect prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the Commission within 30 days after receipt of notification of cancellation.

(B) The surety of insurance must remain in effect until the Commission has terminated the license.

(iv) *Internal reserve.* Internal reserve is a fund established and maintained by the periodic deposit or crediting of a prescribed amount into an account or reserve which is not segregated from licensee assets and is within the licensee's administrative control in which the total amount of the periodic deposits or funds reserved plus accumulated earnings would be sufficient to pay for decommissioning at the time termination of operation is expected. This method may use negative net salvage value depreciation in which funds are invested in licensee assets, and at the end of facility life, bonds are issued against these assets and the funds raised are used to pay for decommissioning. An internal reserve may also be in the form of an internal sinking fund which is similar to an external sinking fund except that the fund is held and invested by the licensee.

(3) For licensees other than an electric utility, acceptable methods of providing financial assurance for decommissioning are—

(i) Prepayment;

(ii) An external sinking fund, in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund.

(iii) A surety mehtod or insurance;

(iv) In the case of Federal, State, or local government licensees, certification that the appropriate government entity will be guarantor of decommissioning funds; and

(v) Other funding methods which are demonstrated by the applicant or licensee to provide comparable assurance to methods listed in paragraphs (k)(3) (i) through (iv) of this section.

(4) For an electric utility, acceptable methods of providing financial assurance for decommissioning are—

(i) Prepayment;

(ii) An external sinking fund in which deposits are made at least annually;

(iii) A surety method or insurance;

(iv) For an electric utility owning more than one generating facility, an internal reserve in which deposits are made at least annually; and

(v) Other funding methods which are demonstrated by the applicant or licensee to provide comparable assurance to methods listed in paragraphs (k)(4) (i) through (iv) of this section.

18. Section 50.51 is revised to read as follows:

§ 50.51 Duration of license, renewal.

Each license will be issued for a fixed period of time to be specified in the license but in no case to exceed 40 years from the date of issuance. Where the operation of a facility is involved the Commission will issue the license for the term requested by the applicant or for the estimated useful life of the facility if the Commission determines that the estimated useful life is less than the term requested. Where construction of a facility is involved, the Commission may specify in the construction permit the period for which the license will be issued if approved pursuant to § 50.56. Licenses may be renewed by the Commission upon the expiration of the period. Unless application for renewal has been made, application for termination of license pursuant to § 50.82 must be made no later than one year prior to the license expiration date.

19. Section 50.54 is amended by adding new paragraphs (cc) and (dd) to read as follows:

§ 50.54 Conditions of licenses.

Whether stated therein or not, the following shall be deemed conditions in every license issued:

* * * * *

(cc)(1) Each holder of an operating license for a production or utilization facility issued on or after [insert a date 2 years after the effective date of the final rule] shall provide financial assurance for decommissioning in accordance with an approved decommissioning funding plan or by means of a certification as provided in § 50.33(k)(1).

(2) On or before [insert a date two years after the effective date of the final rule], each holder of an operating license for a production or utilization facility in effect on [insert date immediately preceding the date two years after the effective date of the final rule] shall submit information on providing financial assurance for decommissioning as specified in § 50.33(k). Upon approval of a decommissioning funding plan by the Commission, the licensee shall implement procedures for providing financial assurance for decommissioning in accordance with the plan. In each certification of financial assurance, the licensee shall indicate that the means of providing financial assurance for decommissioning are in place.

(3) A decommissioning funding plan will be approved if it includes sufficient information to demonstrate that a reasonable level of assurance will be provided that funds will be available when needed to cover the costs of decommissioning.

(4) Each licensee shall at or about 5 years prior to the projected end of operation submit a cost estimate for decommissioning based on an up-to-date assessment of the actions necessary for decommissioning and, if necessary, plans for adjusting levels of funds assured for decommissioning.

(dd) Each licensee shall keep records of information important to the safe and effective decommissioning of the facility in a file explicitly for this purpose until the license is terminated by the Commission. If records of relevant information are kept for other purposes, reference to these records and their locations may be substituted. Information the Commission considers important to decommissioning consists of—

(1) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when significant contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.

(2) As-built drawings and modifications of structures and equipment in high radiation areas and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

20. Section 50.55 is amended by revising paragraph (c) to read as follows:

§ 50.55 Conditions of construction permits.

Each construction permit shall be subject to the following terms and conditions:

* * * * *

(c) Except as modified by this section and § 50.55a, the construction permit shall be subject to the same conditions to which a license is subject, not including § 50.54(cc).

* * * * *

21. Section 50.82 is revised to read as follows:

§ 50.82 Applications for termination of licenses.

(a) Any licensee may apply to the Commission for authority to surrender a license voluntarily and to decommission the facility. For a facility that permanently ceases operation after [insert effective date of the final rule] this application must be made within two years following permanent cessation of operations, and in no case later than one year prior to expiration of the operating license. Each application for termination of license must be accompanied, or preceded, by a proposed decommissioning plan. For a facility which has permanently ceased operation prior to [insert effective date of the final rule], requirements for contents of the decommissioning plan as specified in paragraphs (b) through (d) of this section may be modified with approval of the Commission to reflect the fact that the decommissioning process has previously been initiated.

(b) The proposed decommissioning plan must include—

(1) The choice of the alternative for decommissioning with a description of activities involved. Alternative methods for decommissioning which significantly delay completion of decommissioning such as use of a storage period, will be acceptable if sufficient benefit results;

(2) A description of controls and limits on procedures and equipment to protect

occupational and public health and safety;

(3) A description of the planned final radiation survey;

(4) An updated cost estimate for the chosen alternative for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and plan for assuring the availability of adequate funds for completion of decommissioning.

(c) Decommissioning plans which propose an alternative that delays completion of decommissioning by including a period of storage or long-term surveillance must provide that—

(1) Funds needed to complete decommissioning be placed into an account segregated from licensee assets and outside the licensee's administrative control during the storage or surveillance period, or a surety method or fund certification be maintained in accordance with the criteria of § 50.33(k); and

(2) Means be included for adjusting cost estimates and associated funding levels over the storage or surveillance period.

(d) For decommissioning plans in which the major dismantlement activities are delayed by first placing the facility in storage, planning for these delayed activities may be less detailed. Updated detailed plans must be submitted and approved prior to the start of these activities.

(e) If the decommissioning plan demonstrates that the decommissioning will be performed in accordance with the regulations in this chapter and will not be inimical to the common defense and security or to the health and safety of the public, and after notice to interested persons, the Commission will issue an order authorizing the decommissioning.

(f) The Commission will terminate the license if it determines that—

(1) The decommissioning has been performed in accordance with an approved decommissioning plan and any conditions in the order authorizing decommissioning; and

(2) The terminal radiation survey and associated documentation demonstrates that the facility and site are suitable for release for unrestricted use.

PART 51—ENVIRONMENTAL PROTECTION REGULATIONS FOR DOMESTIC LICENSING AND RELATED REGULATORY FUNCTIONS

22. The authority citation for Part 51 continues to read as follows:

Authority: Sec. 161, 68 Stat. 948, as amended (42 U.S.C. 2201); secs. 201, as amended, 202, 88 Stat. 1242, as amended, 1244 (42 U.S.C. 5841, 5842).

Subpart A also issued under National Environmental Policy Act of 1969, secs. 102, 104, 105, 83 Stat. 853–854, as amended (42 U.S.C. 4332, 4334, 4335); and Pub. L. 95–604, Title II, 92 Stat. 3033–3041. Section 51.22 also issued under sec. 274, 73 Stat. 688, as amended by 92 Stat. 3036–3038 (42 U.S.C. 2021).

§ 51.20 [Amended]

23. Section 51.20 is amended by removing paragraphs (b) (5) and (10).

24. Section 51.22 is amended by adding a new paragraph (c)(19) to read as follows:

§ 51.22 Criterion for and identification of licensing and regulatory actions eligible for categorical exclusion.

* * * * *

(c) The following categories of actions are categorical exclusions:

* * * * *

(19) Approvals of decommissioning funding plans.

25. In § 51.53 paragraph (b) is revised to read as follows:

§ 51.53 Supplement to Environmental Report.

(b) *Post operating license stage.* Each applicant for a license amendment authorizing the decommissioning of a production or utilization facility covered by § 51.20 and each applicant for a license or license amendment to store spent fuel at a nuclear power reactor after expiration of the operating license for the nuclear power reactor shall submit with its application the number of copies, as specified in § 51.55, of a separate document, entitled "Supplement to Applicant's Environmental Report—Post Operating License Stage," which will update "Applicant's Environmental Report—Operating License Stage," as appropriate, to reflect any new information or significant environmental change associated with the applicant's proposed decommissioning activities or with the applicant's proposed activities with respect to the planned storage of spent fuel. Unless otherwise required by the Commission, in accordance with the generic determination in § 51.23(a) and the provisions in § 51.23(b), the applicant shall only address the environmental impact of spent fuel storage for the term of the license applied for. The "Supplement to Applicant's Environmental Report—Post Operating License Stage" may incorporate by reference any information contained in "Applicant's Environmental Report—Construction Permit Stage," "Supplement to Applicant's Environment Report—Operating License Stage," final environmental impact statement, supplement to final environmental impact statement or records of decision previously prepared in connection with the construction permit or operating license.

26. In § 51.55, paragraph (a) is revised to read as follows:

§ 51.55 Environmental Report—Number of copies; Distribution.

(a) Each applicant for a license to construct and operate a production or utilization facility covered by paragraphs (b)(1), (b)(2), (b)(3) or (b)(4) of § 51.20 and each applicant for a license amendment authorizing the decommissioning of a production or utilization facility covered by § 51.20, and each applicant for a license or license amendment to store spent fuel at a nuclear power reactor after expiration of the operating license for the nuclear power reactor shall submit to the Director of Nuclear Reactor Regulation or the Director of Nuclear Material Safety and Safeguards, as appropriate, forty-one (41) copies of an environmental report, or any supplement to an environmental report. The applicant shall retain an additional 109 copies of the environmental report or any supplement to the environmental report for distribution to parties and Boards in the NRC proceeding, Federal, State, and local officials and any affected Indian tribes, in accordance with written instructions issued by the Director of Nuclear Reactor Regulation or the Director of Nuclear Material Safety and Safeguards, as appropriate.

* * * * *

27. Section 51.60 is amended by revising paragraph (a) and adding a new paragraph (c) to read as follows:

§ 51.60 Environmental Report—Materials licenses.

(a) Each applicant for a license or other form of permission, or an amendment to or renewal of a license or other form of permission issued pursuant to Parts 30, 32, 33, 34, 35, 40, 61, 70 and/or 72 of this chapter, and covered by paragraphs (b)(1)–(b)(6) of this section, shall submit with its application to the Director of Nuclear Material Safety and Safeguards the number of copies, as specified in § 51.66, of a separate document, entitled "Applicant's Environmental Report" or "Supplement to Applicant's Environmental Report," as appropriate. The "Applicant's Environmental Report" shall contain the information specified in § 51.45. If the application is for an amendment to or a renewal of a license or other form of permission for which the applicant has previously submitted an environmental report, the supplement to applicant's environmental report may be limited to incorporating by reference, updating or supplementing the information previously submitted to reflect any significant environmental change, including any significant environmental change resulting from operational experience or a change in operations or proposed decommissioning activities.

* * * * *

(c) An applicant for a license or license amendment to store spent fuel at a nuclear power reactor after expiration of the operating license for the nuclear power reactor shall comply with the requirements for environmental reports in § 51.53(b), instead of the requirements in this section.

§ 51.95 [Amended]

28. In § 51.95, paragraph (b) is revised to read as follows:

* * * * *

(b) *Post operating license stage.* In connection with the amendment of an operating license authorizing the decommissioning of a production or utilization facility covered by § 51.20 or with the issuance, amendment or renewal of a license to store spent fuel at a nuclear power reactor after expiration of the operating license for the nuclear power reactor, the NRC staff will prepare a supplemental environmental impact statement for the post operating license stage or an environmental assessment, as appropriate, which will update the prior environmental review. The supplement or assessment may incorporate by reference any information contained in the final environmental impact statement, the supplement to the final environmental impact statement—operating license stage, or in the records of decision prepared in connection with the construction permit or the operating license for that facility. The supplement will include a request for comments as provided in § 51.73. Unless otherwise required by the Commission, in accordance with the generic determination in § 51.23(a) and the provisions of § 51.23(b), a supplemental environmental impact statement for the post operating license stage or an environmental assessment as appropriate, will address the environmental impacts of spent fuel storage only for the term of the license, license amendment or license renewal applied for.

* * * * *

PART 70—DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

29. The authority section for Part 70 is revised to read as follows:

Authority: Secs. 51, 53, 161, 182, 183, 68 Stat. 929, 930, 948, 953, 954, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2201, 2232, 2233, 2282); secs. 201, as amended, 202, 204, 206, 88 Stat. 1242, as amended, 1244, 1245, 1246 (42 U.S.C. 5841, 5842, 5845, 5846).

Section 70.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 70.21(g) also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 70.31 also issued under sec. 57d, Pub. L. 93-377, 88 Stat. 475 (42 U.S.C. 2077). Sections 70.36 and 70.44 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 70.61 also issued under secs. 186, 187, 68 Stat. 955 (42 U.S.C. 2236, 2237). Section 70.62 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273), §§ 70.3, 70.19(c), 70.21(c) 70.22(a), (b), (d)–(k), 70.24 (a) and (b), 70.32(a) (3), (5), (6), (d), and (i), 70.36, 70.39 (b) and (c), 70.41(a), 70.42 (a) and (c), 70.56, 70.57 (b), (c) and (d), 70.58(a)–(g)(3), and (h)–(j) are issued under sec. 161b, 68 Stat. 948 as amended (42 U.S.C. 2201(b)); §§ 70.7, 70.20a (a) and (d), 70.20b (c) and (e), 70.21(c), 70.24(b), 70.32(a)(6), (c), (d), (e), and (g), 70.36, 70.51(c)–(g), 70.56, 70.57 (b) and (d) and 70.58(a)–(g)(3), and (h)–(j) are issued under sec. 161i, 68 Stat. 949, as amended (42 U.S.C. 2201(i)); and §§ 70.20b (d) and (e), 70.38, 70.51 (b) and (i), 70.52, 70.53, 70.54, 70.55, 70.58 (g)(4), (k), and (l), 70.59 and 70.60 (b) and (c) are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

30. Section 70.4 is amended by adding a new paragraph (x) to read as follows:

§ 70.4 Definitions.

* * * * *

(x) "Decommission" means to remove (as a facility) safely from service and reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of license.

31. Section 70.22 is amended by adding a new paragraph (a)(9) to read as follows:

§ 70.22 Contents of applications.

(a) Each application for a license shall contain the following information: * * *

* * * * *

(9) As provided by § 70.25, certain applications for specific licenses filed under this part must contain a proposed decommissioning funding plan or a certifiction of financial assurance for decommissioning. In the case of renewal applications submitted before [insert a date one year after the effective date of the final rule] this submittal may follow the renewal application but must be submitted on or before [insert a date one year after the effective date of the final rule].

* * * * *

32. Section 70.23 is amended by adding a new paragraph (a)(12) to read as follows:

§ 70.23 Requirements for the approval of applications.

(a) An application for a license will be approved if the Commission determines that:

* * * * *

(12) The applicant's proposed decommissioning funding plan or certification of financial assurance for decommissioning, if required by § 70.25 (a) or (b), includes sufficient information to demonstrate that the proposed funding method will provide reasonable assurance that sufficient funds will be available to decommission the facility in a safe and timely manner.

* * * * *

33. A new § 70.25 is added to read as follows:

§ 70.25 Financial assurance for decommissioning.

(a) Each applicant for a specific license authorizing the possession and use of unsealed special nuclear material in quantities exceeding 10^5 times the applicable quantities set forth in Appendix C of Part 20 shall submit a decommissioning funding plan as described in paragraph (d) of this section. Each holder of such a license shall provide financial assurance for decommissioning; required submittals for providing financial assurance are set out in § 70.32(k)(2).

(b) Each applicant for or holder of a specific license authorizing possession and use of unsealed special nuclear material in quantities specified in paragraph (c) of this section shall either—

(1) Submit a decommissioning funding plan as described in paragraph (d) of this section; or

(2) Submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by paragraph (c) of this section using one of the methods described in paragraph (e) of this section. For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but prior to the receipt of licensed material.

(c) Table of required amounts of financial assurance for decommissioning by quantity of material.

Greater than 10^4 but less than or equal to 10^5 times the applicable quantities of Appendix C of Part 20	$500,000

Greater than 10^3 but less than or equal to 10^4 times the applicable quantities of Appendix C of Part 20	100,000

(d) Each decommissioning funding plan must contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning including means of adjusting cost estimates and associated funding levels over the life of the facility.

(e) Financial assurance for decommissioning must be provided by one or more of the following methods:

(1) *Prepayment.* Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets that will retain their value over the projected operating life of the facility and that are in amount such that the principal plus accumulated earnings would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

(2) *A surety method or insurance.* A surety method or insurance is a guarantee that decommissioning costs will be paid should the licensee default. A surety method may be in the form of a surety bond, letter of credit, line of credit, secured interest, or other guarantee method. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

(i) The surety or insurance must be open-ended or, if written for a specified term, such as five years, must be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the Commission, the beneficiary, and the licensee of its intention not to renew. The surety or insurance must also provide that the beneficiary may automatically collect prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the Commission within 30 days after receipt of notification of cancellation.

(ii) The beneficiary of the surety or insurance must be trustee acceptable to the Commission such as an appropriate state or federal government agency or a major financial organization.

(iii) The surety or insurance must remain in effect until the Commission has terminated the license.

(3) An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by the periodic deposit of a prescribed amount into an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of the periodic deposits plus accumulated earnings would be sufficent to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

(4) In the case of Federal, State, or local government licensees, a certification that the appropriate government entity will be guarantor of decommissioning funds.

(5) Other funding methods which are demonstrated by the applicant or licensee to provide comparable assurance to methods listed in paragraphs (c)(1) through (3) of this section.

34. Section 70.32 is amended by adding new paragraphs (k) and (l) to read as follows:

§ 70.32 Conditions of licenses.

* * * * *

(k)(1) Each holder of a specific license issued on or after [insert a date 1 year after the effective date of the final rule] which is of a type described in § 70.25(a) or (b), shall provide financial assurance for decommissioning in accordance with the criteria set forth in § 70.25.

(2) On or before [insert a date 1 year after the effective date of the final rule] each holder of a specific license of a type described in § 70.25(a) shall submit a decommissioning funding plan or certification of financial assurance for decommissioning in an amount at least equal to $500,000 in accordance with the criteria set forth in § 70.25. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan at this time, the licensee shall include a decommissioning funding plan in any application for license renewal.

(3) On or before [insert a date 1 year after the effective date of the final rule] each holder of a specific license of a type described in § 70.25(b) shall submit a certification of financial assurance for decommissioning or a decommissioning funding plan in accordance with the criteria set forth in § 70.25.

(4) As of [insert a date 1 year after the effective date of the final rule] each licensee covered by § 70.25 (a) or (b) shall provide financial assurance for decommissioning as a condition of license. If a decommissioning funding plan has been submitted to the Commission, implementing the plan becomes a condition of the license upon approval of the plan.

(l) Each person licensed under this part shall keep records of information important to the safe and effective decommissioning of the facility in a file explicitly for this purpose until the license is terminated by the Commission. If records of relevant information are kept for other purposes, reference to these records and their locations may be substituted. Information the Commission considers important to decommissioning consists of—

(1) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when significant contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms and concentrations.

(2) As-built drawings and modifications of structures and equipment in high radiation areas and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

35. Section 70.38 is revised to read as follows:

§ 70.38 Expiration and termination of licenses.

(a) Except as provided in § 70.33(b) and paragraph (e) of this section, each specific license expires at the end of the day, in the month and year stated in the license.

(b) Each licensee shall notify the Commission promptly, in writing under § 70.5, and request termination of the license when the licensee decides to terminate all activities involving materials authorized under the license. This notification and request for termination of the license must include the reports and information specified in paragraphs (c)(1 (iv) and (v) of this section and a plan for completion of decommissioning if required by paragraph (c)(2) of this section or by license condition.

(c)(1) If a licensee does not submit an application for license renewal under § 70.33, the licensee shall on or before the expiration date specified in the license—

(i) Terminate use of special nuclear material;

(ii) Remove radioactive contamination to the extent practicable except for those procedures covered by paragraph (c)(2)(i) of this section;

(iii) Properly dispose of special nuclear material;

(iv) Submit a completed form NRC-314, which certifies information concerning the disposition of materials, and

(v) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates that the premises are suitable for release for unrestricted use in some other manner. The licensee shall, as appropriate—

(A) Report levels of radiation in units of microrads per hour of beta and gamma radiation at one centimeter and gamma radiation at one meter from surfaces, and report levels of radioactivity in units of disintegrations per minute (or microcuries) per 100 square centimeters removable and fixed for surfaces, microcuries per milliliter for water, and picocuries per gram for solids such as soils or concrete; and

(B) Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

(2)(i) In addition to the information required under paragraphs (c)(1) (iv) and (v) of this section, the licensee shall submit a plan for completion of decommissioning if the procedures necessary to carry out decommissioning have not been previously approved by the NRC, are extensive, and could significantly increase potential health and safety impacts to workers or to the public such as in cases where—

(A) Workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation; or

(B) Procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

(C) Procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation; or

(D) Procedures would involve techniques not applied routinely during maintenance operations.

(ii) Procedures with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

(iii) The proposed decommissioning plan, if required by paragraph (c)(2)(i) of this section or by license condition, must include—

(A) Discussion of planned decommissioning activities;

(B) Description of methods used to assure protection of workers and the environment against radiation hazards during decommissioning;

(C) A description of the planned final radiation survey; and

(D) An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and plan for assuring the availability of adequate funds for completion of decommissioning.

(iv) The proposed decommissioning plan will be approved by the Commission if the information therein demonstrates that the decommissioning will be completed as soon as is reasonable and that the health and safety of workers and the public will be adequately protected.

(3) Upon approval of the decommissioning plan by the Commission, the licensee shall complete decommissioning in accordance with the approved plan. As a final step in decommissioning, the licensee shall again submit the information required in paragraph (c)(1)(v) of this section and shall certify the disposition of accumulated wastes from decommissioning.

(d) If the information submitted under paragraphs (c)(1)(v) or (c)(3) of this section does not adequately demonstrate that the premises are suitable for release for unrestricted use, the Commission will inform the licensee of the appropriate further actions required for termination of license.

(e) Each specific license continues in effect beyond the expiration date if necessary with respect to possession of residual special nuclear material present as contamination until the Commission notifies the licensee in writing that the license is terminated. During this time, the licensee shall—

(1) Limit actions involving special nuclear material to those related to decommissioning; and

(2) Continue to control entry to restricted areas until they are suitable for release for unrestricted use and the Commission notifies the licensee in writing that the license is terminated.

(f) Specific licenses will be terminated by written notice to the licensee when the Commission determines that—

(1) Special nuclear material has been properly disposed;

(2) Reasonable effort has been made to eliminate residual radioactive contamination, if present, and

(3)(i) A radiation survey has been performed which demonstrates that the premises are suitable for release for unrestricted use; or

(ii) Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release for unrestricted use.

PART 72—LICENSING REQUIREMENTS FOR THE STORAGE OF SPENT FUEL IN AN INDEPENDENT SPENT FUEL STORAGE INSTALLATION

36. The authority citation for Part 72 is revised to read as follows:

Authority: Secs. 51 53, 57, 62, 63, 65, 69, 81 161, 182, 183, 184, 186, 187, 189, 68 Stat. 929, 930, 932, 933, 934, 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2077, 2092, 2095, 2099, 2111, 2201, 2232, 2233, 2234, 2236, 2237, 2239, 2282); sec. 274, Pub. L. 86–273, 73 Stat. 688, as amended by (42 U.S.C. 2021); secs. 201, as amended, 202, 206, 68 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); Pub. L. 95–601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851)

37. Section 72.3 is amended by adding a new paragraph (y) to read as follows:

§ 72.3 Definitions.

* * * * *

(y) "Decommission" means to remove (as a facility) safely from service and reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of license.

38. Section 72.14 is amended by revising paragraph (e)(3) to read as follows:

§ 72.14 Contents of application: General and financial information.

* * * * *

(e) * * *

(3) Estimated decommissioning costs, and the necessary financial arrangements to provide reasonable assurance prior to licensing that decommissioning will be carried out after the removal of spent fuel from storage.

* * * * *

39. Section 72.18 is revised by revising paragraph (b) and adding a new paragraph (c) to read as follows:

§ 72.18 Decommissioning plan, including financing.

* * * * *

(b) The decommissioning plan must contain information on how reasonable assurance will be provided that funds will be available to decommission the

ISFSI. This information must include a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning including means of adjusting cost estimates and associated funding levels over the life of the ISFSI.

(c) Financial assurance for decommissioning must be provided by one or more of the following methods:

(1) *Prepayment.* Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets that will retain their value over the projected operating life of the ISFSI and that are in amount such that the principal plus accumulated earnings would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposits of government securities.

(2) *A surety method or insurance.* A surety method or insurance is a guarantee that decommissioning costs will be paid should the licensee default. A surety method may be in the form of a surety bond, letter of credit, line of credit, secured interest, or other guarantee method. Any surety method or insurance used to provide financial insurance for decommissioning must contain the following conditions:

(i) The surety or insurance must be open-ended or, if written for a specified term, such as five years, must be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the Commission, the beneficiary, which shall be a Commission-approved trustee, and the licensee of its intention not to renew. The surety or insurance must also provides that the beneficiary may automatically collect prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the Commission within 30 days after receipt of notification of cancellation.

(ii) The surety or insurance must remain in effect until the Commission has terminated the license.

(3) An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by the periodic deposit of a prescribed amount into an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of the periodic deposits plus accumulated earnings would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

(4) In the case of Federal, State, or local government licensees certification that the appropriate government entity will be guarantor of decommissioning funds.

(5) Other funding methods which are demonstrated by the applicant or licensee to provide comparable assurance to methods listed in paragraphs (c) (1) through (3) of this section.

40. In § 72.33 new paragraphs (b) (6) and (7) are added to read as follows:

§ 72.33 License conditions.

* * * * *

(b) Every license issued under this part shall be subject to the following conditions, even if they are not explicitly stated therein:

* * * * *

(6) The licensee shall implement procedures for providing financial assurance for decommissioning in accordance with the approved preliminary decommissioning plan.

(7) Each licensee shall keep records of information important to the safe and effective decommissioning of the facility in a file explicitly for this purpose until the license is terminated by the Commission. If records of relevant information are kept for other purposes, reference to these records and their locations may be substituted. Information the Commission considers important to decommissioning consists of—

(i) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when significant contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.

(ii) As-built drawings and modifications of structures and equipment in high radiation areas and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

* * * * *

41. Section 72.38 is revised to read as follows:

§ 72.38 Applications for termination of licenses.

(a) Any licensee may apply to the Commission for authority to surrender a license voluntarily and to decommission the ISFSI. This application must be made within two years following permanent cessation of operations, and in no case later than one year prior to expiration of the license. Each application for termination of license must be accompanied, or preceded, by a proposed final decommissioning plan.

(b) The proposed final decommissioning plan must include—

(1) The choice of the alternative for decommissioning with a description of activities involved. Alternative methods for decommissioning which significantly delay completion of decommissioning, such as use of a storage period, will be acceptable if sufficient benefit results;

(2) A description of controls and limits on procedures and equipment to protect occupational and public health and safety;

(3) A description of the planned final radiation survey; and

(4) An updated detailed cost estimate for the chosen alternative for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and plan for assuring the availability of adequate funds for completion of decommissioning including means for adjusting cost estimates and associated funding levels over any storage or surveillance period.

(c) For final decommissioning plans in which the major dismantlement activities are delayed by first placing the ISFSI in storage, planning for these delayed activities may be less detailed. Updated detailed plans must be submitted and approved prior to the start of such activities.

(d) If the final decommissioning plan demonstrates that the decommissioning will be performed in accordance with the regulations in this chapter and will not be inimical to the common defense and security or to the health and safety of the public, and after notice to interested persons, the Commission will issue an order authorizing the decommissioning.

(e) The Commission will terminate the license if it determines that—

(1) The decommissioning has been performed in accordance with an approved final decommissioning plan and any conditions in the order authorizing decommissioning; and

(2) The terminal radiation survey and associated documentation demonstrates that the ISFSI and site are suitable for release for unrestricted use.

Dated at Washington, D.C. this 5th day of February 1985.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

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50 FR 13797
Published 4/8/85
Comment period expires 7/8/85

Licenses and Radiation Safety Requirements for Well-Logging Operations

See Part 39 Proposed Rule Making

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50 FR 23025
Published 5/30/85
Extended comment period expires 7/12/85.

10 CFR Parts 30, 40, 50, 51, 70, and 72

Decommissioning Criteria for Nuclear Facilities; Extension of Comment Period

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule: Extension of comment period.

SUMMARY: On February 11, 1985, (50 FR 5600), the Nuclear Regulatory Commission published for public comment a proposed rule setting forth technical and financial criteria for decommissioning licensed facilities. The proposed amendments addressed decommissioning planning needs, alternatives, timing, funding methods, and environmental review requirements. The Department of the Army, the Department of Energy of the State of Oregon and other interested parties have requested an extension in order to fully evaluate the issues raised and develop comments on the proposed rule. In view of the importance of the proposed rule, the amount of time suggested by the requestors to complete their review and the desirability of developing a final rule as soon as practicable, the NRC has decided to extend the comment period for an additional 60 days. The original comment period for this proposed rule expired on May 13, 1985.

DATE: The extended comment period expires July 12, 1985. Comments received after the date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before that date.

ADDRESSES: Submit written comments to the Secretary of the Commission, Washington, DC 20555, Attention: Docketing and Service Branch. Copies of comments received may be examined at the NRC Public Document Room, 1717 H Street, NW, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Keith G. Steyer or Catherine R. Mattsen, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 443-7910.

Dated at Washington, DC, this 24th day of May, 1985.

Samuel J. Chilk,

Secretary of the Commission.

➤**50 FR 23960**
Published 6/7/85
Comment period expires 10/7/85.

10 CFR Parts 30, 40, 61, 70, and 72

Financial Responsibility Requirements Applicable to NRC Licensees for Cleanup of Accidental and Unexpected Releases of Radioactive Materials

AGENCY: Nuclear Regulatory Commission.

ACTION: Advance notice of proposed rulemaking (ANPRM).

SUMMARY: The Nuclear Regulatory Commission is considering whether to amend its regulations to require certain persons licensed to possess nuclear materials to demonstrate that they possess adequate financial means to pay for cleanup of accidental releases of radioactive materials. If licensees lack adequate financial resources and funds are not available for prompt cleanup, the consequences could be potentially significant for the public, the licensee, and the Federal government. This advance notice of proposed rulemaking is being issued to invite advice and recommendations on several questions pertaining to this proposal concerning scope of coverage, as well as the availability and cost to licensees of obtaining the various forms of financial assurance.

DATE: Comment period expires October 7, 1985. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received before this date.

ADDRESSES: Send comments or suggestions to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

Hand deliver comments to: Room 1121, 1717 H St. NW., Washington, DC between 8:15 a.m. and 5:00 p.m.

Examine copies of comments received at: The NRC Public Document Room, 1717 H Street NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mary Jo Seeman, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 427-4647.

SUPPLEMENTARY INFORMATION:

Background

Purpose and Scope

This ANPRM is seeking guidance on requiring certain classes of materials licensees to demonstrate evidence of financial responsibility for cleanup of accidental releases, i.e., an unauthorized release of radioactive materials due to human error, system failure, an act of God, or defective components. Licensees under consideration in this ANPRM include radiopharmaceutical manufacturers, industrial radiographers, users of gauging devices, gas chromatography, well-logging, nuclear medicine diagnosis and radiation therapy. Other NRC licensed operations covered by this ANPRM include fuel cycle activities such as uranium milling, UF_6 production, and fuel processing and fabrication. Regulated waste management activities include commercial low-level waste disposal, independent spent fuel storage facilities, and persons disposing or storing of their own waste under special license conditions.[1] If implemented, such standards would be a matter of compatibility with the Agreement States.

The financial assurance program for cleanup of accidental release being considered by the Commission in this ANPRM is separate and distinct from the compensation program mandated by the Commission regulations pursuant to the Price-Anderson Act, which does not provide funds for cleanup per se. Currently, the Price-Anderson program applies only to nuclear reactors on a mandatory basis and to plutonium processors and fuel fabricators on a discretionary basis.[2] These activities and uses of materials would not be included in the proposed program. The program proposed in this ANPRM is not intended to provide compensation to persons for personal injury or property damage and is, therefore, not a public liability program.

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[1] The proposed financial responsibility program would exempt the following Department of Energy facilities: High-level waste repositories (licensed under 10 CFR Part 60), independent spent fuel storage facilities, and monitored retrievable storage facilities (both licensed under 10 CFR Part 72). In the event of an accident, DOE has access to public funds to pay for cleanup. Additionally, DOE private contractors working at the repository can be indemnified under section 170(d) of the Atomic Energy Act.

[2] The Commission has authority under section 170 of the Atomic Energy Act to apply Price-Anderson indemnification to any category of licensee whenever the Commission deems it advisable in the

Moreover, it appears that the Comprehensive Environmental Response, Compensation and Liability Act of 1980, "CERCLA" (Pub. L. 96–510) would not provide cleanup funds for releases involving NRC licensees. In a **Federal Register** notice issued on September 8, 1983, (48 FR 40658) EPA made the following policy statement:

> EPA has also chosen not to list releases of source, byproduct, and special nuclear material from any facility with a current license issued by the Nuclear Reglatory Commission (NRC), on the grounds that the NRC has full authority to require cleanup of releases from such facilities.

This ANPRM is soliciting public comments on the advisability of having NRC require financial responsibility for prompt cleanup of radioactive materials both on-site and off-site after accidental or unexpected contamination by fuel cycle and other materials licensees. Any necessary environmental restoration would also be included.[3] Accidental or unexpected contamination refers to an unauthorized release of radioactive materials in excess of NRC regulatory limits regardless of the cause of the release. Examples of causes include human error or negligence, an act of God, licensee misconduct, system failure, or defective components.

This ANPRM focuses on whether to require licensees to demonstrate financial responsibility for cleanup of accidental or unexpected releases of radioactive meterials and not for authorized and predictable activities normally associated with decommissioning. The latter is being addressed in a separate ongoing Commission rulemaking on decommissioning.

Need for Action

Although there is little information available on the financial condition of NRC fuel cycle and materials licensees, the NRC staff believes most of these licensees already have some financial resources or insurance coverage for on-site and off-site cleanup as a prudent business practice.

However, if a licensee did not have adequate financial resources, and an accidental or unexpected contamination did occur, there could be both short and long term adverse public health and safety consequences from the radioactive contamination, as well as loss of use of conaminated property. Moreover, from an equity viewpoint, the Commission believes it appropriate that the licensee, and not the public, should assume financial responsibility for prompt cleanup of accidental releases caused by licensee activities.

The issue of licensee financial responsibility for cleanup of accidental releases of radioactive materials has also been an issue with the States; the Conference of Radiation Control Program Directors has recognized the need for Federal standards since at least 1976. In August of 1984, in order to promote intergovernment consultation at an early stage of a proposed agency action, the Commission sent a draft version of this ANPRM to officials in all fifty States, and also asked for their comments. Commission staff also discussed the issue of the ANPRM with State radiation control program officials in October, 1984. The comments generally supported the development of the rulemaking, and specific comments were incorporated into the ANPRM.

Both NRC and Agreement State licensees have had accidental or unexpected releases of radioactive materials that have been costly to cleanup. State and Federal estimates for cleanup costs have been estimated at up to $2,000,000 for a single event. Examples of some of these cleanup costs that the NRC staff is aware of include:

—In 1983, a cesium-137 sealed source was accidentally ruptured. Workers inadvertently spread the contamination into residences and public buildings. The cost for cleanup of this contamination was estimated to be at least $500,000.

—In 1982, an americium-241 sealed source in use in a well-logging operation was inadvertently ruptured, resulting in contamination of both on-site drilling equipment and off-site homes and commercial residences. Cleanup costs were estimated to be up to at least $1,000,000.

—During 1979 and 1980, a tritium manufacturer's operations in Tucson, Arizona resulted in releases both on and offsite. The company was financially unable to pay for cleanup, and State officials estimated that the State spent approximately $2,000,000 in labor and capital costs for removal and cleanup of the tritium.

Relatively little data on cleanup costs for accidental releases of licensees is available in NRC records, mainly because this type of information is not required to be submitted to the agency. However, a recent review of NRC unusual events reports for radioactive releases by materials and fuel cycle licensees indicates that from 1980 to 1983, accidental or unexpected releases from licensees' operations believed to involve significant cleanup costs (more than a few thousand dollars) involved fewer than one percent annually of the total fuel cycle and materials licensees authorized to possess and use byproduct, source and special materials.

Besides lacking a comprehensive data base for licensee cleanup costs for accidental releases, the Commission also has no available records to determine if licensees lack (or previously lacked) adequate funds to provide for prompt cleanup of accidental releases. Accordingly, the Commission is using this ANPRM to solicit public and industry input on the scope and magnitude of the problem. However, even given this lack of a strong data base, the NRC staff does not believe it is prudent for the Commission to wait until an event occurs which requires expensive cleanup to consider the development of a regulation. Other agencies, such as the U.S. Environmental Protection Agency, have gone forward with financial responsibility requirements in the absence of a large documented data base.

In addition, several NRC-funded studies have presented cost estimates for cleanup of NRC-licensed fuel cycle facilities related to emergency planning issues and the Price-Anderson Act.[4] Since these studies were prepared for different purposes and assumptions, it is difficult to compare the results or to use their conclusions as the basis for estimating cleanup costs for the vast majority of fuel cycle and material licensees. Therefore, the NRC staff is proposing to use the limited, but actual,

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exercise of its licensing authority. However, the Commission has not chosen to extend Price-Anderson indemnification to materials licensees with the single exception of those engaged in the use of plutonium in a plutonium processing and fuel fabrication plant.

[3] Environmental restoration following an accidental release into or upon the land or water is intended to provide limited coverage for the damage or destruction of natural resources.

[4] See J. P. McBride, "Economic Consequences of Accidental Releases from Fuel Fabrication and Radioisotope Processing Plants," prepared by Oak Ridge National Laboratories for the U.S. Nuclear Regulatory Commission, 1979, (NUREG/CR–0222); the results of the study were discussed in a U.S. Nuclear Regulatory Commission Information Report, "Extension of Indemnity Coverage To Materials Licensees Other Than Those Processing And Using Plutonium," (SECY–80–487), October 10, 1980. See also H. K. Elder, Working Paper, "Technology, Safety and Costs of Decommissioning Reference Nuclear Fuel Cycle and Non-Fuel Cycle Facilities Following Postulated Accidents," Pacific Northwest Laboratory, NURGE/CR–3293, August, 1983.

past cleanup cost experience (discussed previously) as the basis for setting the amount of financial responsibility coverage in this ANPRM. The NRC staff will consider, at a later date, the issue of financial responsibilities for the small number of licensees who have the potential to be involved in the significantly more costly cleanups postulated in the NRC-funded studies.

Regulatory Precedents

A variety of State and Federal agencies have enacted financial responsibility requirements to provide assurance that funds are available for cleanup of accidental releases of various substances. Federal agencies have enacted requirements pursuant to the Motor Carrier Act, (Pub. L. 96–296), the Resource Conservation and Recovery Act, (Pub. L. 94–580), the Federal Water Pollution Control Act of 1972, (Pub. L. 92–500), Surface Mining Control and Reclamation Act of 1977 (Pub. L. 95–87), Outer Continental Shelf Lands Act, (Pub. L. 95–372), the Trans-Alaska Pipeline Authorization Act of 1973 (Pub. L. 93–153), and the Deep-Water Port Act of 1974 (Pub. L. 93–627).

The stipulated dollar requirements vary from $10,000 to over $5,000,000 for these different programs. As an example, the 1984 minimum levels of financial responsibility for motor carriers transporting hazardous substances ranges from between $1,000,000 to $5,000,000 (Motor Carrier Act of 1980). The EPA regulations for financial responsibility for owners and operators of hazardous waste facilities (40 CFR Parts 264 and 265, Subpart H) require coverage of $1,000,000 dollars for each sudden occurrence, with an annual aggregate of at least $2,000,000, and $3,000,000 for each nonsudden occurrence, with an annual aggregate of at least $6,000,000 (Subtitle C—Hazardous Waste Management, Resource Conservation and Recovery Act).

Impacts

The Commission is aware that, if promulgated, the potential rule could impact a variety of parties. Before the Commission would implement the financial responsibility requirement, it would assure itself, on the basis of the information gathered from the public comments as well as additional study by the NRC staff, that the health and safety benefits of such a requirement would outweigh the costs imposed on licensees and the public.

If licensee funds are not promptly available for cleanup, public funds might have to be directly expended by State and Federal agencies. Even without a bankrupt licensee, there could be significant public impacts if cleanup is delayed by ensuing litigation over the responsibility and cost.

As previously mentioned, the NRC staff believes that most materials licensees have adequate financial resources for prompt cleanup of accidental releases as a matter of prudent business practice. This proposed rulemaking would have the most significant impact on those licensees who may not be able to provide adequate financial assurances. Accordingly, the staff is especially interested in hearing from those licensees who feel they cannot demonstrate that they have sufficient resources to assure cleanup of accidental releases.

The cost to NRC licensees for meeting the financial requirements for prompt cleanup would vary, depending on the level of funding and on the type of financial assurance mechanism selected. There are a variety of possible legal instruments and arrangements that could be used to demonstrate that a licensee possesses adequate resources to provide funds for prompt cleanup of accidental releases of radioactive materials. They include insurance, trust funds, surety or performance bonds, escrow accounts, certificates of deposits, deposits of securities, letters of credit, a parent company guarantee, and an analysis of the licensee's financial condition.

The most expensive approach would require that a licensee put aside 100% of the estimated cost of cleanup. Examples of this approach include cash deposits, or deposits of securities. Less expensive approaches involve purchasing an insurance policy or financial instrument from a third party, such as an insurance company, bank, or financial institution with a face amount equal to the estimated costs of cleanup. Specific costs of the various financial mechanisms are not easily obtained from licensees or from the financial and insurance institutions. Accordingly, the NRC is specifically interested in obtaining comments on the costs of these types of financial instruments in this ANPRM.

The proposed regulatory requirement would also impact NRC resources. The logistics and resource costs for amending thousands of materials licensees would be significant. The requirement would also entail an agency administrative effort for recordkeeping, auditing, and enforcement. However, the proposed financial assurance requirement could also avert substantial NRC costs resulting from lengthy enforcement proceedings and/or litigation against licensees unable to assure prompt cleanup.

Summary of Features Being Considered for Proposed Rule

The Commission is seeking comments in this ANPRM on a proposal that would require certain fuel cycle and materials licensees to demonstrate adequate financial resources for cleanup of accidental releases of radioactive materials on-site and off-site. Financial responsibility would cover cleanup for both property and environmental restoration (see footnote 3). For purposes of initial discussion, the Commission is considering a $2,000,000 baseline as the required maximum amount of financial responsibility for materials and fuel cycle facilities. This figure was chosen because it is in the range of known cleanup costs for NRC licensees and of other stated dollar amounts of State and Federal financial responsibility requirements for cleanup of accidental releases (See "Regulatory Precedents"). The amount would be adjusted to reflect changes in inflation and technology.

The Commission will consider, at a later date, the issue of financial responsibility for the small number of licensees who have the potential to be involved in the significantly more costly cleanups postulated in the NRC funded studies referenced in footnote 4.

The proposed rule would have the following features:

1. The transporting of radioactive material by common and contract carriers covered by the financial responsibility requirements of the Motor Carrier Act of 1980 (Pub. L. 96–296) would be excluded.
2. Financial responsibility would cover both sudden and nonsudden accidental releases and would exclude authorized and predictable activities normally associated with decommissioning. Additionally, if a licensee were required to demonstrate financial responsibility for both decommissioning and cleanup of accidental releases, he could not use the same financial assurance to guarantee both commitments. The latter is being covered by the Commission's decontamination and decommissioning rulemaking.
3. Financial responsibility would cover on-site and off-site cleanup for private and public property, as well as environmental restoration of natural resources.
4. Licensed State, Federal government, or other self-insured public authorities would be excluded.

5. Types of possible acceptable financial assurances that the Commission staff is considering include:

a. Standard comprehensive general liability insurance.

b. Environmental impairment liability insurance.

c. Conventional property insurance.

d. Non-Price Anderson nuclear liability and property insurance.

e. Cash or negotiable securities held by a third party, such as a trust, or escrow account.

f. A financial test.

g. A surety or performance bond.

h. A corporate guarantee from a parent company.

Specific Considerations

Advice and recommendations on the Commission's proposed action are invited from all interested persons, and specifically, from licensees, State officials, and representatives of the finance and insurance industry. Comment is also invited on which licensees should be considered for exemption from this proposed requirement, as well as the availability, cost, and applicability of the various financial assurance mechanisms to provide adequate financial assurances for cleanup of accidental releases.

1. Describe the extent and nature of financial responsibility problems, if any, for the cleanup of accidental releases by materials licensees.

2. Assuming the need for the resolution of financial responsibility problems for the cleanup of accidental releases, the Commission is seeking comments and supporting reasons on the following questions:

a. What criteria (such as half-life, physical form, type of encapsulation, and amount of radioactive material) should NRC use for determining the amount of coverage to be required for different classes of licensees?

b. What effect would the cost of this coverage have on licensee operations?

c. How large should the financial responsibility requirement be? Should there be a uniform minimum amount, or a "sliding scale" requirement, to match the financial requirements to the actual risks of various types and quantities of materials possessed, or the financial size of the licensee? If so, what criteria are suggested in this regard?

d. One basis for determining the amount of coverage being considered under the Commission's proposed rulemaking would be the characteristics of the licensed material. Should the Commission exempt licensees with certain types or quantities of radioactive materials, such as those with short half-lives with low activities? If so, what cutoff criteria should be applied?

e. Should the Commission consider increasing the amount of coverage for licensees whose facilities have poor safety and/or inspection histories?

f. What criteria (such as ensuring that the funds will be promptly available when needed) should NRC use in evaluating financial assurance mechanisms?

g. How should the financial protection be provided to ensure that it will be available if needed?

h. With regard to comprehensive general liability and environmental impairment liability policies, the Commission staff is especially interested in hearing from offerers of these policies regarding the availability of their insurance for specified nuclear risks, as well as the terms and conditions of these types of insurance. What is the availability and premium cost of these types of policies (as well as facility form liability coverage from the nuclear insurance pools) to provide cleanup coverage for off-site sudden and nonsudden accidental or unexpected releases of radioactive materials from licensee operations, including damage to natural resources? Are the terms and conditions of these existing types of policies appropriate for covering the risks of accidental nuclear releases? If not, would the insurance industry provide this type of coverage?

i. What is the cost and availability of property insurance from the conventional insurance market and the nuclear insurance pools to provide cleanup coverage for sudden and nonsudden on-site accidental or unexpected releases of radioactive materials from materials licensees? Are the terms and conditions of these existing types of policies appropriate for covering the risks of accidental nuclear releases? If not, would the insurance industry provide this type of coverage?

j. Are there financial assurance mechanisms and insurance policies currently available to provide coverage for environmental restoration of natural resources?

k. How can the Commission ensure that funds for cleanup are promptly available when an accidental release occurs, while still preserving the rights of guarantors to evaluate whether such claims for cleanup are legitimate?

The Commission is particularly interested in hearing from both regulatory agencies with a history of administering financial responsibility programs, as well as financial and insurance institutions on this issue. Furthermore, if it appears that there is going to be a delay before the guarantor will provide funds for cleanup, and prompt cleanup is necessary for health and safety reasons, are there other avenues for cleanup funds available to the Commission or other responsible State or Federal agency?

l. Should the Commission also consider requiring licensees to provide evidence of financial responsibility for the non-radiological component of cleanup of an accidental release?

m. How should the Commission consider setting up such a program so that it is promptly notified when there is a change in the financial status of the licensee?

n. Should the Commission consider differentiating between intentional and accidental releases?

o. What amount of coverage would be appropriate for those fuel fabrication and radioisotope processing plants which have the potential for accidents resulting in cleanup costs significantly higher than $2 million?

List of Subjects

10 CFR Part 30

Byproduct material, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Penalty, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 40

Government contracts, Hazardous materials—transportation, Nuclear materials, Penalty, Reporting and recordkeeping requirements, Source material, Uranium.

10 CFR Part 61

Low-level waste, Nuclear materials, Penalty, Waste treatment and disposal.

10 CFR Part 70

Hazardous materials-transportation, Nuclear materials, Packaging and containers, Penalty, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Security measures, Special nuclear material.

10 CFR Part 72

Manpower training programs, Nuclear materials, Occupational safety and health, Security measures, Spent fuel, Reporting and recordkeeping requirements.

The authority citation for this document is:

Authority: Sec. 161, Pub. L. 83–703, 68 Stat. 948 as amended (42 U.S.C. 2201).

Dated at Washington, D.C., this 4th day of June, 1985.

For the Nuclear Regulatory Commission

Samuel J. Chilk,

Secretary of the Commission.

PART 30 • PROPOSED RULE MAKING

>50 FR 30616
Published 7/26/85
Comment period expires 11/18/85.

Medical Use of Byproduct Material

See Part 35 Proposed Rule Making

PART 30

RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

PETITIONS FOR RULE MAKING

42 FR 40791
Published 8/11/77
Comment Period expires 10/11/77

[Docket No. PRM-30-55]

STATE OF NEW JERSEY, DEPARTMENT OF ENVIRONMENTAL PROTECTION

Filing of Petition for Rulemaking

Notice is hereby given that the State of New Jersey through its Department of Environmental Protection, by letter dated May 31, 1977, has filed with the Nuclear Regulatory Commission a petition for rulemaking.

The petitioner requests the Commission to:

(a) Establish criteria to quantify the "as low as readily achievable" emission reduction policy for major facilities using byproduct materials from man-made fission reactions and require existing plants to meet these criteria;

(b) Establish siting criteria for all such facilities as a basis for the evaluation of the acceptability of new plant locations in terms of radiation doses to the general public; and

(c) Require all existing and new byproduct material facilities to develop and implement off-site environmental surveillance programs so that the NRC and all other interested persons have current information as to the levels of radioactivity in the environment around such facilities.

The petitioner states that the Commission has radiation standards and criteria for facilities using byproduct material from man-made fission reactions as raw materials which differ drastically from the standards for nuclear power plants. The petitioner makes a comparison between a nuclear power plant and a radiopharmaceutical plant and states that a nuclear power plant, with its sophiscated control equipment, is designed to handle a number of different types of potential accidents and still keep the radiation exposure to the public within acceptable limits. The petitioner states further that a radiopharmaceutical plant does not have the same capabilities and an accident, should it occur, could release greater quantities of radioactive material into the environment than would occur during normal operating conditions.

In further support of the petition the petitioner states that because byproduct material plants have unrestricted siting, there are many more people in the vicinity of the byproduct material plants than near nuclear power plants. The petitioner asserts that the use of better controlled equipment than that presently installed would not only reduce the normal radiation exposure to the public, but would also be insurance against the adverse health consequences of an accidental release.

A copy of the petition for rulemaking is available for public inspection in the Commission's Public Document Room, 1717 H Street NW., Washington, D.C.

A copy of the petition for rulemaking may be obtained by writing to the Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

All interested persons who desire to submit written comments or suggestions concerning the petition for rulemaking should send their comments to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch, by October 11, 1977.

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46 FR 35662
Published 7/10/81
≫ Withdrawn 9/21/83

10 CFR Parts 20, 30, 40, and 70

[Docket No. PRM-30-58]

Receipt of Petition for Rulemaking From the National Bureau of Standards, Department of Commerce

AGENCY: Nuclear Regulatory Commission.

ACTION: Publication of a petition for rulemaking.

SUMMARY: The Nuclear Regulatory Commission is publishing a petition for rulemaking from the National Bureau of Standards, U.S. Department of Commerce. The petition suggests alternative amendments to NRC regulations that would exempt radioactive material obtained directly or indirectly from environmental sources from specific license application requirements. The suggested amendments would facilitate environmental standards activity for the NBS and remove potential ambiguity in the application of NRC regulations.

DATE: Comment period expires September 8, 1981.

ADDRESSES: A copy of the petition for rulemaking is available for public inspection in the Commission's Public Document Room, 1717 H Street, NW., Washington, DC. A copy of the petition may be obtained by writing to the Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

All persons who desire to submit written comments concerning the petition for rulemaking should send their comments to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

FOR FURTHER INFORMATION CONTACT: J. M. Felton, Director, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: 301-492-7211.

SUPPLEMENTARY INFORMATION: The Nuclear Regulatory Commission (NRC) received a petition for rulemaking from the National Bureau of Standards, U.S. Department of Commerce on May 14, 1981. The petition has been assigned Docket No. PRM-30-58. The petition suggests amendments to NRC regulations that would "* * * make the ownership, possession, manufacture, production, transfer, receipt, acquisition, and use of any radioactive material obtained directly or indirectly from environmental sources (that is soil, water, air, biota) generally permitted without a requirement for specific application to the Commission. * * *"

The petitioner states, in part that "* * * Because of the plutonium and americium content of soil, tissue, etc., * * * once an environmental sample has passed through a licensee's hands the material is subject to all NRC requirements. Specifically, anyone receiving this material from the initial licensee would have to have a specific license. * * *"

The petitioner intends to provide a variety of environmental standards which would be collected from a variety of places in North America, assayed as to the content for a number of isotopes, and packaged for sale as standards. Under existing regulations and NRC's licensing interpretation, this process could require license applications to the NRC. As the petitioner states, the samples would "* * * include $^{239-240}$Pu, ^{241}Am, Th, U, ^{60}Co, ^{137}Cs, ^{55}Fe. * * * Typical activity levels are 2 to 4 dpm per gram of Pu, U, and Th and 0.1 dpm per gram of ^{241}Am.

The problem would be further accentuated if some sort of chemistry were done on the samples to concentrate the radioactive components such as might occur at an intermediate stage of an analysis procedure."

The petitioner submits two alternative solutions to the problem. Although a specific solution addressing the plutonium and americium content of the environmental sample would solve NBS's specific problem, a broader alternative would remove potential ambiguity in the regulations as they might apply to individuals not normally covered by them. The NRC may adopt either alternatives or both alternatives together.

The NRC requests public comment on this petition for rulemaking. The public may comment on either alternative or a combination of both alternatives. The alternative amendments are as follows:

Alternative 1

Add the following statement as the last sentence in §§ 20.2, 30.1, and 70.2 and as paragraph (e) in § 40.13:

"Radioactive material derived from the sampling of environmental sources are not subject to the provisions of this part."

In connection with this option the petitioner states, "* * * It is presumed a working definition of sampling can be derived which would not include mining and milling operations and similarly a definition of environmental sources which would exclude waste streams and such of licensed activities. To alleviate concern relating to total activity, the definition of sampling can be qualified so that the total sample activity is specified not to exceed 10 CFR 30.71 limits, where they exist."

Alternative 2

1. Add the following entry to § 30.70:

§ 30.70 Schedule A—Exempt concentrations.

Element (atomic number)	Isotope	Col. I gas concentration µCi/ml[1]	Col. II liquid and solid concentration µCi/ml[2]
* * *	*	*	*
Alpha emitting byproduct material, non-specific		2×10^{-14}	1×10^{-8}
* * *	*		*

2. Add the following entry to § 30.71:

§ 30.71 Schedule B.

Byproduct material	Microcuries
* * * * * *	*
Alpha emitting byproduct material, non-specific	0.001
* * * * * *	*

In connection with this option the petitioner would include appropriate cross references in 10 CFR Parts 40 and 70.

Dated at Washington, DC this 6th day of July 1981.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

PART 30

RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

STATEMENTS OF CONSIDERATION

30 FR 8185
Published 6/26/65
Effective 8/25/65

On December 17, 1964, the Commission issued for public comment (29 F.R. 17915) a proposed recodification of its regulations—"Licensing of Byproduct Material", 10 CFR Part 30 and "Radiation Safety Requirements for Radiographic Operations", 10 CFR Part 31. Public comments indicate that the recodification is a desirable step toward simplifying the format of these regulations. Public comments also included some additional suggestions for further revisions of Parts 30 and 31. These suggested changes are being evaluated by the Commission staff in conjunction with other revisions which may be published at a later date.

In the recodification, common requirements applicable to all byproduct material licensing are retained in Part 30 while the remainder of the sections are relocated in proposed new parts designated Parts 31,[1] 32, 33, 34, 35, and 36, each of which is applicable to certain classes or categories of uses or users of byproduct material. The requirements of Parts 31–36 are in addition to those of Part 30 and other applicable provisions in the Commission's regulations.

The parts as recodified are:

Part 30—Rules of General Applicability to Licensing of Byproduct Material. This part includes licensing and related provisions which apply generally to all byproduct material users, licensees or applicants for licenses, and includes such matters as definitions; exemptions; general requirements for specific licenses; common terms and conditions of licenses; inspections, records and tests; and enforcement procedures.

Part 31—General Licenses for Certain Quantities of Byproduct Material and Byproduct Material Contained in Certain Items. This part includes general licenses for quantities of and items containing byproduct material. It does not include general licenses for export and certain of the general licenses for import, which are set out in Part 36, or general licenses for medical uses which are set out in Part 35.

Part 32—Specific Licenses to Manufacture, Distribute, or Import Exempted and Generally Licensed Items Containing Byproduct Material. This part includes the special requirements applicable to specific licenses to manufacture, distribute, or import byproduct material or items containing byproduct material for distribution to persons exempted under Part 30 or generally licensed under Parts 31 or 35.

Part 33—Specific Licenses of Broad Scope for Byproduct Material. This part includes provisions applicable to licenses for multiple quantities and types of byproduct material under which activities involving the use of byproduct material in processing for distribution and research and development are carried on.

Part 34—Licenses for Radiography and Radiation Safety Requirements for Radiographic Operations. This part includes the licensing requirements for use of sealed sources in radiography (presently set out in § 30.24 (g) of Part 30) and the radiation safety requirements for persons holding licenses for radiography now contained in Part 31.

Part 35—Human Uses of Byproduct Material. This part includes the special requirements for (1) licensing of individual physicians for human use of byproduct material, (2) licensing of human use of byproduct material in sealed sources and (3) licensing of human use of byproduct material in institutions, now set out in § 30.24 (a), (b) and (c) of Part 30. It also includes a general license for medical use of certain quantities of byproduct material, now set out in § 30.29.

Part 36—Export and Import of Byproduct Material. This part includes the requirements for specific licenses, the general licenses and other provisions relating to export and import of byproduct material.

A cross-reference table has been placed at the end of each part to permit easy comparison of the old regulations with the new. Parts 30–36 include the substance of applicable rules or amendments adopted and made effective during the period between the date of the notice (Dec. 17, 1964), and the effective date of the rule set forth below. The text of the amendment set forth below is substantially the same as the text of the proposed rule published on December 17, 1964, except for the following:

1. The text of § 30.12 (§ 30.6 of the present regulation) has been revised to reflect the amendment of § 30.6 which was published in the Federal Register on October 20, 1964, and became effective January 18, 1965.

2. The text of § 31.5 (30.21(c) of the present regulation) and § 32.51 (30.24(f) of the present regulation) has been revised to reflect the amendments of §§ 30.21(c) and 30.24(f) which were published in the Federal Register on January 7, 1965, and became effective February 6, 1965.

3. The text of § 30.16 (30.12 of the present regulation) and § 31.7 (30.21(d) of the present regulation) §§ 32.15, 32.16, 32.17, 32.40, 32.52, 32.54, 32.55, 32.56, 32.101 (30.24(j) and 30.24(m) of the present regulation) has been revised to reflect the amendments of §§ 30.12, 30.21 (d), 30.24(j), and 30.24(m) which were published in the Federal Register on March 13, 1965, and became effective April 12, 1965.

4. The text of § 30.14 (30.9 of the present regulation) has been revised to reflect the amendments of § 30.9 which were published in the Federal Register on April 3, 1965, to be effective May 3, 1965.

5. The text of §§ 36.21 (30.33(b) of the present regulation), has been revised to reference the list of countries in § 36.50, Schedule A, rather than referencing "* * * Cuba or countries or areas now or hereafter listed as Subgroup A countries or destinations in § 371.3 of the comprehensive export schedule of the United States Department of Commerce (15 CFR 371.3)." The term "Subgroup A countries" is no longer used in the export regulations of the Department of Commerce. Other minor editorial changes have been made in Part 36.

6. The text of Part 32 has been revised to include § 32.70 (30.24(k) of the present regulation) and Part 35 has been revised to include § 35.31 (30.29 of the present regulation). §§ 30.24(k) and 30.29 were added to Part 30 by amendments which were published in the Federal Register on May 13, 1965, to be effective June 12, 1965.

The purpose of the recodification of Part 30 is to simplify and clarify the format of the present regulations, so that persons subject to byproduct material licensing regulations can conveniently use and understand them. No substantive changes have been made and the requirements under the present regulations are not changed by the recodification.

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[1] The provisions of present Part 31 are incorporated in a Part 34, and Part 31 is reassigned to General Licenses for Certain Quantities of Byproduct Material and Byproduct Material Contained in Certain Items.

Pursuant to the Atomic Energy Act of 1954, as amended, and the Administrative Procedure Act of 1946, the Commission is amending Chapter I of Title 10 of the Code of Federal Regulations by deleting Parts 30 and 31 and substituting therefor new Parts 30, 31, 32, 33, 34, 35, and 36 reading as hereinafter set forth. This amendment is published as a document subject to codification to be effective sixty (60) days after publication in the FEDERAL REGISTER.

31 FR 5315
Published 4/2/66
Effective 5/2/66

Exemption of Tritium Contained in Certain Items

On September 17, 1965, the Atomic Energy Commission published in the FEDERAL REGISTER (30 F.R. 11923) proposed amendments to its regulations which would have extended the current exemptions from Commission licensing requirements for tritium contained in certain specified items, to include tritium contained in thermostat dials and pointers, radio dials and pointers, automobile shift quadrants and marine compasses.

Interested persons were invited to submit written comments and suggestions for consideration in connection with the proposed amendments within 60 days after publication of the notice of proposed rule making in the FEDERAL REGISTER. Comment opposing the use of tritium on radio dials and pointers questioned whether the usefulness of tritium on radio dials and pointers would justify increased exposure of the general public from widespread use of tritium for this purpose.

Following consideration of the comments and other factors involved, the Commission approved amendments to 10 CFR Part 30, Rules of General Applicability to Licensing of Byproduct Material which exempt from the licensing requirements of section 81 of the Atomic Energy Act of 1954, as amended, and from the requirements of Parts 20 and 30–36 of the Commission's regulations, the receipt, possession, use, transfer, export, ownership or acquisition of thermostat dials and pointers, automobile shift quadrants and marine compasses containing tritium. The Commission deferred action on an amendment which would exempt radio dials and pointers containing tritium.

The exemptions provided in these amendments do not apply to the manufacture or to the import for sale or distribution of these items. The amendments to 10 CFR Part 32, Specific Licenses to Manufacture, Distribute, or Import Exempted and Generally Licensed Items Containing Byproduct Material, set forth criteria for the issuance of specific licenses to manufacture or import such items and certain reporting and quality control requirements applicable to holders of such specific licenses. With respect to reporting of material transfers (§ 32.16), the amendment set forth below requires licensees who import to report the total quantity of licensed material imported, rather than the total quantity of material transferred, as specified in the proposed amendment. In addition, the requirement of proposed § 32.16, that licensees identify by name and address all persons to whom a total of more than 5 curies of tritium or promethium 147 was distributed during the reporting period, has been omitted.

The Commission has found that, under the conditions specified in the amendments, the exemptions will not constitute an unreasonable risk to the common defense and security and to the health and safety of the public.

The Commission has determined that these items are intended for use by the general public. Accordingly, pursuant to § 150.15(a)(6) of 10 CFR Part 150, Exemptions and Continued Regulatory Authority in Agreement States under section 274, the transfer of their possession or control by the manufacturer, processor, or producer is subject to the Commission's licensing and regulatory requirements even if the product is manufactured pursuant to an agreement State[1] license. A manufacturer, processor, or producer of such items when located in an agreement State should file an application with the Commission for a specific license authorizing the transfer of such items. The application should meet the criteria of § 32.14 (b), (c), and (d).

Pursuant to the Atomic Energy Act of 1954, as amended, and the Administrative Procedure Act of 1946, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Parts 30 and 32, are published as a document subject to codification, to be effective thirty (30) days after publication in the FEDERAL REGISTER.

32 FR 785
Published 1/24/67
Effective 2/23/67

Exemption of Tritium Contained in Marine Navigational Instruments

On September 14, 1966, the Atomic Energy Commission published in the FEDERAL REGISTER (31 F.R. 12023) a proposed amendment to § 30.15(a)(5), 10 CFR Part 30 of its regulations which would have exempted from licensing requirements the possession and use of marine navigational instruments containing not more than 250 millicuries of tritium gas. In addition, the proposed amendment would have required the tritium content of the marine compasses presently exempted by § 30.15(a)(5) to be in the physical form of gas.

Interested persons were invited to submit written comments and suggestions for consideration in connection with the proposed amendment within 60 days after publication of the notice of proposed rule making in the FEDERAL REGISTER. After consideration of the comments received and other factors involved, the Commission has adopted the proposed amendment. The text of the amendment set out below is identical with the text of the proposed amendment published September 14, 1966.

The exemption set out in the amendment to Part 30 does not apply to the manufacture or import for sale or distribution of the marine navigational instruments. Certain criteria for the issuance of a specific license to manufacture or import such exempted items and certain reporting and quality control requirements are set forth in §§ 32.14, 32.15, 32.16, and 32.110, 10 CFR Part 32, "Specific Licenses to Manufacture, Distribute, or Import Exempted and Generally Licensed Items Containing Byproduct Material." The Commission has determined that marine navigational instruments are items intended for use by the general public. Accordingly, pursuant to § 150.15(a)(6) of 10 CFR Part 150, "Exemptions and Continued Regulatory Authority in Agreement States Under section 274," the transfer of their possession or control by the manufacturer, processor, or producer is subject to the Commission's licensing and regulatory requirements even if the product is manufactured pursuant to an agreement State[1] license. A manufacturer, processor, or producer of marine navigational instruments containing tritium, when located in an agreement State, would be required to file an application with the Commission for a specific license authorizing the transfer of such instruments. The application should meet the criteria of § 32.14 (b), (c), and (d), 10 CFR Part 32.

The exemption of marine navigational instruments containing not more than 250 millicuries of tritium gas is consistent with the consumer product criteria published in the FEDERAL REGISTER on March 16, 1965 (30 F.R. 3462), which sets out the essential terms of the Commission's policy with respect to the approval of the use of byproduct and source material in products intended for use by the general public without the imposition of regulatory controls on the user. The Commission has found that, under the conditions specified in the amendment, the exemption will not constitute an unreasonable risk to the common defense and security and to the health and safety of the public.

Pursuant to the Atomic Energy Act of 1954, as amended, and the Administrative Procedure Act of 1946, as amended, the following amendment to Title 10, Chapter I, Code of Federal Regulations, Part 30, is published as a document subject to codification to be effective 30 days after publication in the FEDERAL REGISTER.

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[1] A State to which the Commission has transferred certain regulatory authority over radioactive material by formal agreement, pursuant to sec. 274 of the Atomic Energy Act of 1954, as amended.

32 FR 4241
Published 3/18/67
Effective 4/17/67

Exemption of Scandium 46-Labeled Resins for Use in Oil Wells

On December 14 1966, the Atomic Energy Commission published in the Federal Register (31 F.R. 15747) a proposed amendment to 10 CFR Part 30 which would, by a new § 30.16, exempt from licensing and regulatory requirements the use and transfer of resins containing scandium 46 and designed for sand-consolidation in oil wells, when the resins have been manufactured in accordance with a specific license issued pursuant to a proposed new § 32.17 or equivalent regulations of an agreement State. In addition, two amendments to 10 CFR Part 32 were proposed which would set out requirements for Commission issuance of specific licenses for the manufacture or import of such resins. One of the requirements of the proposed new § 32.17 was that the concentration of scandium 46 in the resin will not exceed 1.4×10^{-3} μc/ml. The proposed amendment to § 32.16 would require an annual report by persons licensed under § 32.17 indicating the total quantities of scandium 46 transferred.

Interested persons were invited to submit written comments and suggestions for consideration in connection with the proposed amendments within 30 days after publication of the notice of proposed rule making in the Federal Register. After consideration of the comments received, the Commission has adopted the proposed amendments. The text of the amendments set out below is identical with the text of the proposed amendments published December 14, 1966.

The Commission has found that, under the conditions specified in the amendments, the exemption will not constitute an unreasonable risk to the common defense and security and to the health and safety of the public.

The Commission considers that such resins are not a product intended for use by the general public; therefore, the transfer of such resins in an agreement State by any manufacturer licensed by that agreement State[1] would not be licensed or regulated by the Commission.

Pursuant to the Atomic Energy Act of 1954, as amended, and the Administrative Procedure Act of 1946, as amended, the following amendments of Title 10, Chapter I, Code of Federal Regulations, Parts 30 and 32, are published as a document subject to codification to be effective 30 days after publication in the Federal Register.

32 FR 13920
Published 10/6/67
Effective 10/6/67

Exemption of Promethium 147 Contained in Luminous Timepieces

On May 20, 1964, the Atomic Energy Commission published in the Federal Register (29 F.R. 6562) proposed amendments to 10 CFR Part 30. The proposed amendments would have, among other things, extended the existing exemption for tritium activated timepieces or hands or dials to include such items activated with promethium 147. The proposed amendments would have permitted not more than 100 microcuries of promethium 147 per watch and not more than 500 microcuries per any other timepiece. In addition, limits would have been placed upon the levels of radiation from the promethium 147 activated hands and dials.

Interested persons were invited to submit written comments or suggestions for consideration in connection with the proposed amendments within 60 days after publication. Of the comments received, several opposed the proposed amendments on the ground that possible advantages of promethium 147 over tritium for the proposed uses would not appear to justify the additional exposure of the population to radiation that might occur. Some comments also questioned the advantages claimed by the petitioner. Comments endorsing the proposed amendments were less specific but implied the judgment that advantages in the use of promethium 147 might be expected to outweigh resultant exposures to radiation. After consideration of the comments and other factors involved, the Commission decided not to exempt from licensing at that time the use of promethium 147 in timepieces (30 F.R. 3374).

During 1964 and 1965, the European Nuclear Energy Agency (ENEA) and the International Atomic Energy Agency (IAEA) established a panel to develop international standards for radioluminous timepieces. The resultant standards which apply to timepieces activated with radium, tritium, and promethium 147 were adopted by the Organization of Economic Cooperation and Development Council (OECD) and the IAEA Board of Governors in January 1967. Available information indicates that the Federal Republic of Germany, India, Japan, South Africa, and the United Kingdom have authorized the use of promethium 147 on timepieces.

The international standards for radioluminous timepieces provide for somewhat smaller quantities of promethium 147 for clocks, i.e., a maximum of 200 microcuries rather than 500 microcuries as proposed in the amendment published for comment by the Commission in 1964. The quantity of 100 microcuries which would have been permitted on watches by those amendments is the average quantity per watch recommended in the international standards. It appears that satisfactory illumination can be obtained with the reduced quantities on clocks. The radiation levels and the estimated exposure to the users would be correspondingly reduced. Available data from actual measurements of radiation levels from timepieces containing promethium 147 indicate that the radiation dose to the reproductive tissue of a person continously wearing a watch containing the maximum amount of promethium 147 authorized under the amendment would probably be less than 1 millirem per year.

The Commission has reconsidered the exemption of promethium 147 on timepieces and has decided to adopt the exemption, with a modification to reflect the provisions of the international standards, in the form set forth below. Other changes have been incorporated in the effective amendment published below, which reflect the recodification of 10 CFR Part 30 and other amendments to that part since the notice of proposed rule making was published. The Commission has found that, under the conditions specified in the amendment, the exemption of promethium 147 in timepieces will not constitute an unreasonable risk to the common defense and security and to the health and safety of the public.

The exemption provided by the amendment does not apply to the application of promethium 147 to timepieces, hands or dials, or to the import for sale or distribution of timepieces, hands or dials containing promethium 147. Certain criteria for the issuance of a specific license to manufacture or import such items and certain reporting and quality control requirements are set forth in §§ 32.14, 32.15, 32.16, and 32.110, 10 CFR Part 32, "Specific Licenses to Manufacture, Distribute or Import Exempted and Generally Licensed Items Containing Byproduct Material".

The Commission has determined that timepieces are products intended for use by the general public. Accordingly, pursuant to § 150.15(a)(6) of 10 CFR Part 150, "Exemptions and Continued Regulatory Authority in Agreement States under section 274", the transfer of their possession or control by the manufacturer, processor or producer is subject to the Commission's licensing and regulatory requirements even if the product is manufactured pursuant to an agreement State license.[1] A manufacturer, processor, or producer of promethium 147 activated timepieces, hands or dials, when located in an agreement State would be required to file an application with the Commission for specific license authorizing the transfer of such timepieces, hands or dials. The application should meet the criteria of § 32.14 (b), (c), and (d), 10 CFR Part 32.

The exemption of promethium 147 activated timepieces is consistent with the consumer product criteria published in the Federal Register on March 16, 1965 (30 F.R. 3462), which set out the essential terms of the Commission's policy with respect to the approval of the use of byproduct and source material in products intended for use by the general public without the imposition of regulations on the user.

Since the amendment is intended to provide relief from, rather than to impose, restrictions under regulations currently in effect, it will become effective without the customary 30-day period of notice. Pursuant to the Atomic Energy Act of 1954, as amended, and the Administrative Procedure Act of 1946, as amended, the following amendment to Title 10, Chapter I, Code of Federal Regulations, Part 30, is published as a document subject to codification effective upon publication in the Federal Register. Interested parties may submit written comments on the amendment published below. Comments should be mailed to the Secretary, U.S. Atomic Energy Commission, Washington, D.C. 20545.

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[1] A State to which the Commission has transferred certain regulatory authority over radioactive material by formal agreement, pursuant to section 274 of the Atomic Energy Act of 1954, as amended.

34 FR 6651
Published 4/18/69
Effective 5/18/69

EXEMPTION OF ELECTRON TUBES

On November 14, 1968, the Atomic Energy Commission published in the FEDERAL REGISTER (33 F.R. 16602) proposed amendments to 10 CFR Parts 30, 31, and 32 of its regulations which would (a) exempt from licensing requirements the possession and use of certain electron tubes containing byproduct material, (b) revoke the general license for spark gap and electronic tubes in 10 CFR 31.3, (c) amend the requirements for the issuance of specific licenses for the manufacture or import of certain items containing byproduct material, and (d) amend certain regulatory requirements applicable to holders of such licenses.

Interested persons were invited to submit written comments and suggestions for consideration within 30 days after publication of the notice of proposed rule making in the FEDERAL REGISTER. After consideration of the comments and other factors involved, the Commission has adopted the proposed amendments. The text of the amendments set out below differs from that of the proposed amendments published November 14, 1968, in that:

1. A footnote has been added to § 30.15 (a)(8) to indicate that "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pickup tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents.

2. The exemption for glow lamps containing tritium in § 30.15(a)(7) and the reference to grow lamps containing tritium in § 32.15(c) have been eliminated, since glow lamps have been included in "electron tubes", and thus are exempt under § 30.15(a)(8), as amended.

3. The superscript 1 at the end of § 30.15(a)(3) and the footnote 1 to which it refers have been revoked and a new footnote 1 has been added to § 30.11 to make it clear that the issuance of an exemption by the AEC for export of byproduct material contained in any material or product does not relieve any person from complying with the licensing requirements and regulations of the Department of Commerce applicable to the export of the materials or the products containing such byproduct materials.

Other changes of a nonsubstantive nature have also been made.

The Commission has found that exemption from licensing requirements for the receipt, possession, use, transfer, export, ownership, and acquisition of electron tubes containing not more than 10 millicuries of tritium, 1 microcurie of cobalt-60, 5 microcuries of nickel-63, 30 microcuries of krypton-85, or 5 microcuries of cesium-137 under the conditions set forth below will not constitute an unreasonable risk to the common defense and security and to the health and safety of the public.

Under the provisions of § 150.15(a)(6) of 10 CFR Part 150, "Exemptions and Continued Regulatory Authority in Agreement States Under Section 274," the transfer of possession or control by the manufacturer, processor, or producer of electron tubes distributed for use under the exemption would be subject to the Commission's licensing and regulatory requirements even if the product is manufactured pursuant to an Agreement State license.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Parts 30, 31, and 32, are published as a document subject to codification. The amendments to 10 CFR Parts 30 and 32 shall become effective thirty (30) days after publication in the FEDERAL REGISTER, and the amendment to 10 CFR Part 31 shall become effective ninety (90) days after publication in the FEDERAL REGISTER.

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34 FR 9025
Published 6/6/69
Effective 7/5/69

Exemption of Tritium, Krypton-85 and Promethium-147 in Self-Luminous Products

On June 21, 1968, the Atomic Energy Commission published for comment in the FEDERAL REGISTER (33 F.R. 9198) proposed amendments of 10 CFR Parts 30 and 32 to (a) establish a class exemption from licensing requirements for the use of self-luminous products containing tritium, krypton-85 and promethium-147 when such products have been manufactured, imported, or transferred pursuant to a specific license issued by the Commission authorizing distribution for use under the exemption and (b) establish requirements for the issuance of specific licenses authorizing manufacture, import, or transfer of self-luminous products containing such byproduct material for possession and use under the exemption, and for submission of reports of transfers of byproduct material under such licenses.

All interested persons were invited to submit written comments or suggestions for consideration in connection with the proposed amendments within 60 days after publication of the notice of proposed rule making in the FEDERAL REGISTER.

After careful consideration of the comments received and other factors, the Commission has adopted the amendments set forth below. The only changes from the proposed amendments, other than editorial and clarifying changes, are described below, together with a discussion of the basic features of the amendments.

The amendments of Part 30 exempt, in a new § 30.19, from the licensing and regulatory requirements of the Atomic Energy Act of 1954, as amended, the possession and use of self-luminous products containing tritium, krypton-85, and promethium-147 when such products have been manufactured, processed, produced, imported, or transferred pursuant to a specific license issued by the Commission authorizing transfer for use under the exemption.

The amendments of Part 32 establish, in a new § 32.22, the framework in the Commission's regulations for the issuance of specific licenses to distribute, to persons exempt from licensing requirements, self-luminous products which meet the Commission's safety criteria. An applicant for a license to manufacture, process, produce, import, or transfer self-luminous products for use under the exemption provided by the amendment to Part 30 must, among other things, demonstrate that the safety criteria in § 32.23 would be met.

The safety criteria in § 32.23(a) limit the average dose, or dose commitment, in any one year to members of the group expected to receive the highest dose from normal use and disposal of a single exempt unit, and, in § 32.23(b), limit the dose or dose commitment received by persons engaged in marketing, distributing, and servicing of exempt products, as a result of exposure to the quantities of exempt units likely to accumulate in one location.

A new § 32.23(c) has been added which requires that the product be designed and manufactured so that wear and abuse are unlikely to cause an increase in the potential dose to persons during normal handling and use of the product. Although this requirement was implied in the proposed amendments, or could have been inferred from the information to be submitted in an application for a specific license under § 32.22, the requirement has been specifically included in the safety criteria as adopted.

The limits in the safety criteria for dose or dose commitment to any individual under normal and the most severe conditions, such as accidents or fires, which were published in the notice of proposed rule making, have been restated in an expanded § 32.23(d) in terms of the probability of the failure of the product under such circumstances that a person would receive a dose or dose commitment in excess of the specified doses. These doses are specified to define the degree of risk under accident conditions. The likelihood of persons receiving such doses as a result of failure of any exempt product must be very small. The doses specified are considerably smaller than those that would be likely to produce clinical symptoms of injury. These criteria may have the effect of establishing an upper limit on the amount of radioactive material in the exempt unit.

The probabilities are expressed in terms of the frequency of failure of the containment, shielding, or other safety features of an exempt unit under such circumstances that a person would receive a dose in excess of specified values. The probability of a failure resulting in a dose in excess of the doses referred to in § 32.23(d) may be limited by (1) the ability of the product to withstand severe conditions which it is likely to encounter, (2) the amount of radioactive material present in each exempt unit, (3) the likelihood of occurrence of conditions of sufficient severity to cause failure of the containment, shielding, or other safety features of the product, or (4) any combination of these and other credible circumstances.

Two changes have been made in information to be supplied by an applicant for a specific license to manufacture, process, produce, transfer, or import self-luminous products under § 32.22(a). The distances for measurement of radiation levels have been changed from 1 and 10 centimeters to 5 and 25 centimeters from the external surface of the product and a provision for averaging the radiation levels over an area not to exceed 10 square centimeters has been added in § 32.22(a)(2)(vi). A new item has been added, in § 32.22(a)(2)(xiv), to require the applicant to submit a determination that the probabilities with respect to the doses referred to in § 32.23(d) meet the criteria of that paragraph. The definition of "dose commitment" has been eliminated, since that definition has been included in other amendments to Part 32 published in the Federal Register on April 18, 1969 (34 F.R. 6653). The exemption for self-luminous products (§ 30.19) has been modified to provide that, in addition to toys and adornments, products in which tritium, krypton-85 or promethium-147 is used "primarily for frivolous purposes" are not included in the class exemption.

The Commission has concluded that the overall benefits to be derived from the use of radioactive materials in self-luminous products covered by the amendments, as a class of products, offset the small risk as reflected in the safety criteria.

Petitions for rule making for exemption of self-luminous products which do not meet the conditions of the amendments will be considered on a case-by-case basis.

The Commission has found that, under the conditions specified in the amendments, the exemption will not constitute an unreasonable risk to the common defense and security and to the health and safety of the public.

Under the provisions of § 150.15(a)(6) of 10 CFR Part 150, "Exemptions and Continued Regulatory Authority in Agreement States Under Section 274," the transfer of possession or control by the manufacturer, processor, or producer of self-luminous products distributed for use under the proposed exemption would be subject to the Commission's licensing and regulatory requirements even if the product is manufactured pursuant to an Agreement State license.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of title 5 of the United States Code. the following amendments of 10 CFR Parts 30 and 32 are published as a document subject to codification, to be effective 30 days after publication in the Federal Register.

34 FR 19546
Published 12/11/69
Effective 12/11/69

Miscellaneous Amendments

See Part 20 Statements of Consideration.

35 FR 6425
Published 4/22/70
Effective 5/22/70

On August 10, 1968, the Atomic Energy Commission published in the Federal Register (33 F.R. 11414) proposed amendments to 10 CFR Parts 30, 31, 32, and 35 of its regulations. The proposed amendments to Part 30 would exempt from licensing requirements the receipt, possession, use, transfer, ownership, or acquisition of small quantities of byproduct material. The proposed amendments to Part 31 would revoke the general license for small quantities of byproduct material currently set forth in §§ 31.4 and 31.100. Schedule A. Conforming amendments would also be made to the title and to § 31.2 of 10 CFR Part 31. The proposed amendments to Part 32 would establish (a) criteria for the issuance of specific licenses for the manufacture, processing, production, packaging, repackaging, import or commercial distribution of the exempt quantities of byproduct material, and (b) certain license conditions for these specific licenses. The proposed amendment to Part 35 would clarify that the proposed exempt quantities of byproduct material are not for use in humans.

On the same date, the Commission published (33 F.R. 11413) proposed amendments to 10 CFR Part 20, "Standards for Protection Against Radiation," to conform the byproduct material portions of Appendix C, 10 CFR Part 20, to the quantities to be exempted in Part 30. The proposed amendments would also add americium-241 and change certain other quantities listed in Appendix C, 10 CFR Part 20.

Interested persons were invited to submit written comments and suggestions for consideration in connection with the proposed amendments within 60 days after publication of the notices of proposed rule making in the Federal Register. After consideration of the comments and other factors involved, the Commission has adopted the proposed amendments with certain additions and modifications discussed below.

The quantity of iodine-134 in the proposed schedule of exempt quantities, § 30.71, Schedule B, was incorrectly listed as 100 microcuries and has been reduced to 10 microcuries.

The proposed exempt quantity of carbon-14 in § 30.71, Schedule B, has been reduced from 1,000 microcuries to 100 microcuries. The 1,000-microcurie quantity was derived on the basis of limits on concentrations in air for soluble forms of carbon-14. The reduced quantity reflects consideration in the criteria used to arrive at the scheduled exempt quantities, of a permissible concentration of carbon-14 in air in insoluble form.

The note at the end of proposed § 30.71, Schedule B, was misleading at that location and has been deleted. Clarification that an exempt quantity may be composed of fractional parts of one or more of the exempt quantities in § 30.71, Schedule B, provided that the sum of such fractions does not exceed unity, has been incorporated into § 32.19, the section which sets forth conditions of specific licenses to be issued to commercial suppliers of exempt quantities.

The proposed exemption from licensing requirements for small quantities of byproduct material would not have included the distribution of products containing such material. The effect of revoking the general license, § 31.4 of Part 31, would be to limit distribution of products now being distributed under that general license to specific licensees or to persons exempted or generally licensed by other provisions of AEC regulations, such as the general license for certain measuring, gauging, or controlling devices set forth in § 31.5 of Part 31. In order to emphasize the distinction between the exemption for quantities of byproduct material and exemptions for products containing byproduct material, proposed § 32.18 of Part 32 has been modified to indicate more clearly the types of material which commercial suppliers may distribute as exempt quantities. In addition, a new § 30.15(a)(9) has been added to Part 30 to provide exemption from licensing requirements for possession and use of ionizing radiation measuring instruments containing internal calibration or standardization sources of byproduct material in amounts not exceeding the pertinent schedule of exempt quantities. Such sources, when installed inside instruments, constitute a smaller risk than as separate quantities, and specific provision for their use under exemption is warranted.

In order to avoid causing undue hardship to distributors of other products which are presently being transferred as generally licensed quantities, the revocation of the general license in § 31.4 will not become effective until 6 months after publication of this notice of rule making in the Federal Register. If a petition for exemption of such a product from specific licensing requirements is filed prior to revocation of the general license, the Director of Regulation will consider extending the general license until such time as the petition for exemption is finally determined. The 6-month delay in revocation will also permit commercial suppliers now distributing quantities of byproduct material under the general license, to obtain the required specific licenses or license amendments and to implement requirements regarding labels and brochures.

The terms and conditions of § 31.2(b) applicable to the general licenses for certain devices and equipment (§ 31.3) and for small quantities (§ 31.4) are considered to be of such small significance to the remaining generally licensed devices and equipment that they will be revoked concurrently with revocation of the general license for small quantities, rather than modified to remove references to quantities as was proposed.

Proposed § 32.19(b) has been revised to permit the presentation of some of the information required in a label on immediate containers of exempt quantities to be presented instead on an accompanying brochure. In many cases, it is impractical to put all of the wording on the immediate container because of size or use limitations. Under the revised § 32.19(c), the immediate container of each quantity, or separately packaged fractional quantity, is required, as a minimum, to bear a durable, legible label identifying the isotope and the quantity of radioactivity, as well as the words "Radioactive Material."

Proposed § 32.20 has been revised to clarify the requirement for an annual summary report of the total quantity of each isotope transferred under a specific license issued pursuant to § 32.18. Records must be maintained of individual transactions, indicating the name and address of the recipient and the kinds and quantities of byproduct material transferred, but such detailed information is not required to be included in the annual report. The revised reporting requirement would require the licensee to furnish the specified information or state that no transfers were made during the reporting period.

The rules set forth below would (a) exempt from licensing small quantities of byproduct material, (b) revoke the existing general license for similar quantities of byproduct material, (c) exempt from licensing specified quantities of byproduct material contained in calibration sources installed in ionizing radiation measuring instruments, (d) establish requirements for issuance of specific licenses for distribution of exempt quantities of byproduct material, and (e) clarify wording in Part 35 regarding use of exempt quantities of byproduct material in humans. Persons holding an AEC or an Agreement State byproduct material license authorizing manufacture, processing, or production of byproduct material are authorized under the exemption to make transfers, on a noncommercial basis, of exempt quantities of byproduct material possessed under the license, on an exempt basis. This provision is designed to accommodate the occasional transfers between laboratories of small quantities of byproduct material in tissue samples, bioassay samples, tagged compounds, counting standards, etc., which involve negligible risks. A producer, packager, repackager, or importer who intends to distribute, on a commercial basis, quantities of byproduct material for use under the exemptions, even if licensed to manufacture, process, or produce such quantities by an Agreement State, would be required to obtain a specific license from the Commission authorizing the import or commercial distribution of such quantities. To obtain a license, the applicant must meet the criteria of § 32.18, 10 CFR Part 32.

The Commission has found that the exemption from licensing of small quantities of byproduct material and of ionizing radiation measuring instruments containing certain internal calibration or standardization sources under the conditions set forth in the following amendments will not constitute an unreasonable risk to the common defense and security and to the health and safety of the public.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Parts 30, 31, 32, and 35 are published as a document subject to codification. The amendments to 10 CFR Parts 30, 32, and 35 shall become effective thirty (30) days after publication in the Federal Register, and the amendments to 10 CFR Part 31 shall become effective 6 months after publication in the Federal Register.

35 FR 8820
Published 6/6/70
Effective 6/6/70

Exemption of Microwave Receiver Protector Tubes Containing Tritium

On December 25, 1969, the Atomic Energy Commission published in the Federal Register (34 F.R. 20277) a proposed amendment to its regulation, "Rules of General Applicability to Licensing of Byproduct Material", 10 CFR Part 30, to exempt from licensing requirements the possession and use of microwave receiver protector tubes containing not more than 150 millicuries of tritium.

All interested persons were invited to submit written comments and suggestions for consideration in connection with the proposed amendment within thirty (30) days after publication of the notice in the Federal Register. After consideration of the comments and other factors involved, the Commission has adopted the proposed amendment. The text of the amendment set out below is identical with the text of the proposed amendment published December 25, 1969.

The Commission has found that exemption from licensing requirements for the receipt, possession, use, transfer, export, ownership, and acquisition of microwave receiver protector tubes containing not more than 150 millicuries of tritium under the conditions set forth below will not constitute an unreasonable risk to the common defense and security and to the health and safety of the public.

Under the provisions of § 150.15(a)(6) of 10 CFR Part 150, "Exemptions and Continued Regulatory Authority in Agreement States Under Section 274", the transfer of possession or control by the manufacturer, processor, or producer of microwave receiver protector tubes distributed for use under the exemption would be subject to the Commission's licensing and regulatory requirements even if the product is manufactured pursuant to an Agreement State license.

Since the following amendment relieves from, rather than imposes, restrictions under regulations currently in effect, it will become effective without the customary 30-day notice. Accordingly, pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendment to Title 10, Chapter I, Code of Federal Regulations, Part 30 is published as a document subject to codification effective upon publication in the Federal Register.

36 FR 145
Published 1/6/71
Effective 2/5/71

Fees for Facilities and Materials Licenses

See Part 170 Statements of Consideration.

36 FR 1466
Published 1/30/71
Effective 1/30/71

Miscellaneous Amendments

See Part 20 Statements of Consideration.

36 FR 16898
Published 8/26/71
Effective 9/25/71

EXEMPT QUANTITY OF BARIUM–133

On May 25, 1971, the Atomic Energy Commission published in the Federal Register (36 F.R. 9468) proposed amendments to Parts 20, 30, and 31 of its regulations. The proposed amendments would (a) add a listing of 10 microcuries for barium–133 to the schedule of exempt quantities of byproduct material, § 30.71, Schedule B, 10 CFR Part 30; (b) add a similar listing to Appendix C, 10 CFR Part 20; (c) revoke § 31.4, 10 CFR Part 31 which sets forth the existing general license for small quantities of byproduct material that was extended to accommodate the petition from Nuclear-Chicago Corp.; and (d) amend § 30.18(b), 10 CFR Part 30, to reference the new date of revocation of that general license.

Interested persons were invited to submit written comments and suggestions for consideration in connection with the proposed amendments within 30 days after publication of the notice of proposed rule making in the Federal Register. After consideration of the comments received on the notice of proposed rule making and other factors involved, the Commission has adopted the proposed amendments without modification, as set forth below.

The addition of a listing for barium–133 to § 30.71, Schedule B, 10 CFR Part 30, accommodates two of three items for which Nuclear-Chicago Corp., requested exemption from regulatory control, i.e., a sealed source of barium–133 contained within a Liquid Scintillation Counting System for the purpose of internal calibration and standardization, and a unit identified as a "Thyroid Phantom" containing barium–133 and cesium–137, used to educate medical students and practitioners in the identification of thyroid maladies. A third item was withdrawn from consideration by the petitioner. The Commission considers the "Thyroid Phantom" marketed by Nuclear-Chicago Corp., to be an encapsulated source which, with the inclusion of barium–133 in § 30.71, Schedule B, falls within the specification of items which may be transferred in accordance with a license issued under § 32.18, 10 CFR Part 32, "Specific Licenses to Manufacture, Distribute, or Import Exempted and Generally Licensed Items Containing Byproduct Material", to persons exempt pursuant to § 30.18, 10 CFR Part 30. Following addition of barium–133 to § 30.71, Schedule B, existing § 30.15(a)(9), 10 CFR Part 30, will provide exemption from licensing requirements for such sources in liquid scintillation counters.

Under the amendments and the provision of § 150.15(a)(6), 10 CFR Part 150, "Exemptions and Continued Regulatory Authority in Agreement States Under Section 274", a producer, packager, repackager, or importer who intends to distribute, on a commercial basis, quantities of byproduct material for use under the exemption, even if licensed to manufacture, process, or produce such quantities by an Agreement State, would be required to obtain a specific license from the Commission authorizing the import or commercial distribution of such quantities. To obtain a license, the applicant must meet the criteria of § 32.18, 10 CFR

Part 32. Likewise, a person who intends to incorporate byproduct material into ionizing radiation measuring instruments or to import such products containing byproduct material for sale or distribution to persons exempt pursuant to § 30.15(a)(9), 10 CFR Part 30, would be required to obtain a specific license from the Commission pursuant to § 32.14, 10 CFR Part 32.

The Commission has found that the exemption from licensing of 10 microcuries of barium–133 under the conditions set forth in the regulations will not constitute an unreasonable risk to the common defense and security and to the health and safety of the public.

37 FR 3985
Published 2/25/72
Effective 3/26/72

Miscellaneous Amendments to Chapter

See Part 20 Statements of Consideration.

37 FR 5745
Published 3/21/72
Effective 3/21/72

Prohibition of Site Preparation and Related Activities

See Part 50 Statements of Consideration.

37 FR 9207
Published 5/6/72
Effective 6/5/72

Reporting and Control Requirements for Tritium

On August 24, 1971, the Atomic Energy Commission published for comment in the FEDERAL REGISTER (36 F.R. 16593) proposed amendments of its regulations in 10 CFR Part 30, "Rules of General Applicability to Licensing of Byproduct Material" and 10 CFR Part 150, "Exemptions and Continued Regulatory Authority in Agreement States Under Section 274," which would prescribe new reporting and control requirements for tritium in the possession of Commission and Agreement State licensees. These procedures and reports provide, within reasonable limits and on a current basis, information needed by the Commission in the interest of the common defense and security of the United States as to the flow of tritium into, out of, and within the country, and inventory quantities at various locations.

All interested persons were invited to submit written comments and suggestions for consideration in connection with the proposed amendments within 60 days after publication of the notice of proposed rule making in the FEDERAL REGISTER. After careful consideration of the comments received, and other factors involved, the Commission has adopted the amendments set forth below.

The only difference from the amendments published for comment is the inclusion of an exemption from certain of the control and reporting requirements with respect to tritium imported in devices that are authorized by the Commission to be transferred as license-exempt devices.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments of Title 10, Chapter 1, Code of Federal Regulations, Parts 30 and 150, are published as a document subject to codification, to be effective thirty (30) days after publication in the FEDERAL REGISTER.

38 FR 29314
Published 10/24/73
Effective 10/24/73

Definitions of Units of Radioactivity

See Part 20 Statements of Consideration.

38 FR 33968
Published 12/10/73
Effective 3/11/74

TRANSFER OF RADIOACTIVE MATERIAL

Requirements

The Atomic Energy Commission published in the FEDERAL REGISTER on February 13, 1973 (38 FR 4351) proposed amendments to its regulations in 10 CFR Parts 30, 40, and 70 to specify requirements for the transfer by licensees of byproduct material, source material, and special nuclear material.

Interested persons were invited to submit written comments or suggestions for consideration in connection with the proposed amendments within 45 days after publication of the notice of proposed rule making in the FEDERAL REGISTER.

After consideration of the comments received and other factors involved, the Commission has adopted the proposed amendments to 10 CFR Parts 30, 40, and 70, with certain modifications, and has also amended 10 CFR Parts 31 and 150 to incorporate appropriate cross-references therein to the new and amended sections of Part 30, 40, and 70. The changes in the effective rule from the proposed rule, based primarily on the public comments received, are summarized as follows:

(1) Some Agreement States require registration of devices containing generally licensed radioactive material after receipt of the material. Since such registration provisions do not require verification prior to transfer of the material, §§ 30.41(c), 40.51(c), and 70.42(c) have been modified to require verification only of transferees' general licenses which require the licensee to register with the Commission or an Agreement State prior to receipt of the radioactive material.

(2) A conforming change has been made in § 31.2(a) of 10 CFR Part 31 to include § 30.41 in the list of cross-referenced sections to which the general licenses in 10 CFR Part 31 are subject.

(3) New §§ 70.42(a) (3) and (4) are added to 10 CFR Part 70 to clarify that transfers of special nuclear material may be made to contractors of the Commission and carriers who are exempt from the requirements for a license pursuant to §§ 70.11 and 70.12 of that part and equivalent Agreement State regulations. Paragraph 70.42(a) (3) and (4) are renumbered §§ 70.42(a) (5) and (6), respectively.

(4) A conforming change has been made in § 150.20(b) of 10 CFR Part 150 to include §§ 30.41, 40.51, and 70.42 in the list of cross-referenced sections to which the general license in § 150.20 is subject.

Several suppliers of radioactive material commented that a reasonable time should be permitted for them to set up a transferee verification system and obtain appropriate information from their customers. Accordingly, the effective date of these amendments will be March 11, 1974.

Several commercial suppliers of radioactive material and a trade association indicated resistance on the part of customers to past efforts by the suppliers to obtain licensing information from their customers. These commentators suggested that transferees be required to furnish information for verification of their licensed status in addition to transferors being required to verify the licensed status of transferees. The customer resistance referred to occurred at a time when there was no specific requirement for suppliers to obtain copies of customers' licenses or similar documentation and when not all suppliers were asking for such documentation. However, under the requirements now being added to §§ 30.41 (c) and (d), 40.51 (c) and (d), and 70.42 (c) and (d) for all transferors to verify the licensed status of transferees, if a potential transferee should fail to provide the appropriate verification information to the supplier, the supplier would be precluded from making the transfer. Since this requirement would be imposed on all suppliers and all transfers, this should be ample motivation for transferees to furnish the appropriate information. On the other hand, since suppliers need not transfer radioactive material to any customer who does not furnish appropriate licensing information, it is not necessary to specify in the regulations a requirement for transferees to furnish such information.

Three commentators suggested that the verification of a transferee's authorization to receive radioactive material should refer only to quantity authorized and should not include information on the type and form of radioactive material. Information on type and form of radioactive material is necessary because some licensees are authorized to receive and possess some, but not all, types and forms of materials (e.g., specific radioisotopes, sealed sources or specified radiopharmaceuticals). Accordingly, the amendments which follow retain the requirement for information as to type and form, as well as quantity, of radioactive material which the transferee is authorized to receive.

Two commentators questioned how a supplier would know that a customer's license was current. In practice, very few amendments of AEC licenses revoke or reduce the quantity, type or form of material previously authorized to be possessed. A supplier may assume that a transferee's license which authorizes receipt of the material to be transferred is valid unless he has actual notice that it has been revoked or amended in such manner as to no longer authorize the receipt of the material to be transferred.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendments of Title 10, Chapter I, Code of Federal Regulations, Parts 30, 31, 40, 70, and 150 are published as a document subject to codification.

39 FR 26279
Published 7/18/74
Effective 8/19/74

Environmental Protection; Licensing and Regulatory Policy and Procedures

See Part 51 Statements of Consideration.

40 FR 8774
Published 3/3/75
Effective 3/3/75

Energy Reorganization Act; Revisions to Chapter I to Reflect Organizational and Procedural Changes

See Part 2 Statements of Consideration.

40 FR 50703
Published 10/31/75
Effective 10/31/75

Clarifying and Corrective Amendments to Chapter

Notice is hereby given of the Amendment of the Nuclear Regulatory Commission's regulations in 10 CFR Parts 0, 20, 30, and 70 which are of a minor nature.

The amendments of Part 70 make an editorial change to clarify the definition of "random error" in § 70.57(a) (5), and correct the spelling of "unidirectional" in § 70.57(a) (6).

The amendments of Parts 0 and 20 make minor corrections and editorial changes in §§ 0.735–28(1), 0.735–30(m), 0.735–40(e), and 20.407(a) (3).

The amendment of Part 30 amends § 30.32(a) to require that Form NRC–313, "Application for Byproduct Material License" be filed in duplicate with the Director of Nuclear Material Safety and Safeguards.

Because these amendments relate solely to corrections and minor matters, the Commission has found that good cause exists for omitting notice of proposed rule making, and public procedure thereon, as unnecessary, and for making the amendments effective October 31, 1975.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Parts 0, 20, 30, and 70 are published as a document subject to codification.

41 FR 16445
Published 4/19/76
Effective 4/19/76

Miscellaneous Changes to Chapter

See Part 20 Statements of Consideration.

41 FR 18300
Published 5/3/76
Effective 6/2/76

Preservation of Records

See Part 20 Statements of Consideration.

42 FR 33265
Published 6/30/77
Effective 6/30/77

CERTAIN REPORTING DATES CHANGED

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations to change reporting dates to correspond to the new Federal fiscal year. The NRC data system is maintained on the fiscal year basis. Statements of tritium inventory are changed from December 31 and June 30 to March 31 and September 30 and statements of source material inventory from June 30 to September 30. The only effect of the amendment is that NRC licensees will submit statements of inventory on a different date than at present.

EFFECTIVE DATE: June 30, 1977.

FOR FURTHER INFORMATION CONTACT:

Mr. Eugene Sparks, NRC Division of Safeguards, NMSS, Washington, D.C. 20555, FTS 492–7090 or commercial area code 301.

SUPPLEMENTARY INFORMATION: The U.S. Nuclear Regulatory Commission is amending 10 CFR 30.55(b), "Tritium reports" (By-product material); 10 CFR 40.64(b), "Reports" (Source material); 10 CFR 150.17(b), "Submission to Commission of source material reports" (Agreement States); and 10 CFR 150.19(b), "Submission to Commission of tritium reports" (Agreement States) to change reporting dates. Statements of tritium inventory are changed from December 31 and June 30 to March 31 and September 30 of each year and statements of source material inventory from June 30 to September 30 of each year.

The first reporting date under this change is September 30, 1977. Within 30 days after September 30, 1977 statements shall be made for: (1) Tritium inventory for the period January 1, 1977, through September 30, 1977, a nine month period; and (2) source material inventory for the period July 1, 1976, through September 30, 1977, a fifteen month period. Thereafter, statements for tritium inventory would be submitted for each successive 6 months and statements for source material inventory for each fiscal year, or each successive 12 months.

This change is made because the U.S. Federal Government changed its fiscal year from July 1 through June 30 to October 1 through September 30 and the NRC computer data retrieval system is maintained on a fiscal year basis. Also, the data system is common to both the Energy Research and Development Administration (ERDA) and the NRC. ERDA has changed accordingly. Thus, facilities under the cognizance of both agencies will avoid different dates for record keeping and reporting.

Inasmuch as the amendments set forth below are of a minor nature, good cause exists for omitting notice of proposed rulemaking, and public procedure thereon, as unnecessary and for making the amendments effective on June 30, 1977.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and section 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Parts 30, 40 and 150 are published as a document subject to codification.

43 FR 2386
Published 1/17/78
Effective 2/16/78

PART 30—RULES OF GENERAL APPLICABILITY TO LICENSING OF BYPRODUCT MATERIAL

Exemption of Persons Using Spark Gap Irradiators Containing Cobalt-60

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is exempting from licensing and regulatory requirements persons using nuclear material near the spark gap of oil furnaces to prevent ignition problems. The exemption, requested by Ray Burner Co., does not apply to the manufacture or import of the spark gap irradiators. The exemption covers the use of the spark gap irradiators in electrically ignited fuel oil burners having a firing rate of at least 3 gallons per hour (11.4 liters per hour).

EFFECTIVE DATE: February 16, 1978.

FOR FURTHER INFORMATION CONTACT:

Mr. Jim Henry, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, 301-443-6910.

SUPPLEMENTARY INFORMATION: By letter dated May 18, 1973, the Ray

Burner Co. of San Francisco, Calif., filed a petition for rule making (PRM 30-54) with the Atomic Energy Commission requesting an exemption from licensing requirements for spark gap irradiators containing not more than 1 microcurie of cobalt-60 in plated or alloy form. This notice of rule making responds to the request of Ray Burner Co.

BACKGROUND

On October 24, 1975, the Nuclear Regulatory Commission published in the FEDERAL REGISTER (40 FR 49801) a proposed amendment of its regulation 10 CFR Part 30 which would exempt from licensing and regulatory requirements the receipt, possession, use, transfer, export, ownership, and acquisition of spark gap irradiators containing not more than 1 microcurie of cobalt-60 per spark gap irradiator for use in electrically ignited fuel oil burners.

All interested persons were invited to submit written comments and suggestions for consideration in connection with the proposed amendment and a draft environmental impact statement by December 8, 1975. After consideration of the comments and other factors involved, the Commission has adopted the amendment. The text of the amendment set out below differs from the text of the proposed amendment published October 24, 1975, by excluding from the exemption the use of spark gap irradiators in oil burners having a firing rate of not more than 3 gallons per hour (11.4 liters per hour).

DISCUSSION OF COMMENTS

Two commentators observed that the exemption as proposed did not specifically prohibit use of the spark gap irradiators in domestic oil burners and therefore the potential market is quite large. In the notice published October 24, 1975, the Commission stated (40 FR 49801) that in typical applications, the spark gap irradiators are used in boilers, power plants, and other heavy duty equipment, but not in private home furnaces or internal combustion engines.

The Commission's statement was based on the engineering characteristics of small oil burners (3 gallons per hour maximum main flame input) and their associated safety control timing (90 seconds maximum flame establishing period). A spark delay of more than 90 seconds would be indicative of permanent arc failure (or other malfunction) rather than temporary arc failure attributable to the statistical time lag between impressment of voltage and formation of a spark in an igniter. Because the time lag is statistical, there is a possibility that the delay may be several seconds, but the probability of the delay being 90 seconds or longer is extremely remote.

Based on these factors, there is neither a need nor a market for spark gap irradiators in small automatically fired warm-air furnaces, small floor mounted unit heaters, and similar appliances used in private homes and commercial and industrial establishments. This conclusion is recognized by changing the text of § 30.15(a)(10) to exclude from the exemption the use of spark gap irradiators in oil burners having a firing rate of not more than 3 gallons per hour (11.4 liters per hour). The exemption does not preclude the use of spark gap irradiators in private home oil burners if they have a firing rate greater than 3 gallons per hour (11.4 liters per hour).

DISCUSSION OF FINAL RULE

The Commission has found that exemption from licensing requirments for the receipt, possession, use, transfer, export, ownership, and acquisition of spark gap irradiators containing not more than 1 microcurie of cobalt-60 under the conditions set forth below will not constitute an unreasonable risk to the common defense and security and to the health and safety of the public.

The exemption does not apply to the manufacture or import for sale or distribution of the spark gap irradiators. Criteria for the issuance of a specific license to conduct such activities and quality control and reporting requirements are set forth in §§ 32.14, 32.15, 32.16, and 32.110 of 10 CFR Part 32, "Specific Licenses to Manufacture, Distribute, or Import Certain Items Containing Byproduct Material." Prototype tests for spark gap irradiators containing cobalt-60 are not specified in the regulation. Applicants for specific licenses are required by § 32.14(b)(4) to submit procedures for and results of prototype tests. The Nuclear Regulatory Commission will either approve the tests or require submission of acceptable tests to demonstrate that the material will not become detached from the product and that the byproduct material will not be released to the environment under the most severe conditions likely to be encountered in normal use of the product. The testing requirements will be incorporated into the specific license.

The amendment, in effect, makes the manufacturer or importer responsible for providing an approved product for use in electrically ignited fuel oil burners. The requirement for use in electrically ignited fuel oil burners will be met prior to the transfer of the product for use under § 30.15 by conditioning each specific license issued to the manufacturer or importer with the reqhirement of incorporating a spark gap irradiator containing not more than 1 microcurie of cobalt-60 in either an electrically ignited fuel oil burner or a container labeled with instructions for installation in such a burner. In addition, the manufacturer or importer will be authorized to transfer these spark gap irradiators to a person holding a specific license provided such specific license contains similar transfer conditions to meet the end use requirements of the exemption. The subsequent possession, use, and disposal by all other persons will be exempt from licensing and regulatory requirements of the Commission.

Under the provisions of § 150.15(a)(6) of 10 CFR Part 150, "Exemptions and Continued Regulatory Authority in Agreement States Under Section 274," the transfer of possession or control by persons in Agreement States who manufacture, process, or produce spark gap irradiators containing cobalt-60 for use by exempt persons are subject to the Commission's licensing and regulatory requirements, even though the spark gap irradiators are manufactured under an Agreement State license. Such manufacturers, processors, or producers wishing to transfer possession or control of spark gap irradiators containing cobalt-60 for use by exempt persons will be required to obtain a specific license issued by the Commission under § 32.14 of 10 CFR Part 32.

AVAILABILITY OF FINAL ENVIRONMENTAL STATEMENT

Pursuant to the National Environmental Policy Act of 1969, and the Commission's regulations in 10 CFR Part 51, "Licensing and Regulatory Policy and Procedures for Environmental Protection," the Commission's Office of Standards Development has prepared a final environmental impact statement in connection with this action to amend Part 30 of the Commission's regulations. The statement is available for inspection by the public in the Commission's Public Document Room at 1717 H Street NW., Washington, D.C. In about two weeks after publication of this notice in the FEDERAL REGISTER, copies of the statement will be available as NUREG-0319 from the National Technical Information Service, Springfield, Va. 22161. The price will be $6.00 for paper copy and $3.00 for microfiche.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, and sections 552 and 553 of title 5 of the United States Code, the following amendment to Title 10, Chapter I, Code of Federal Regulations, Part 30 is published as a document subject to codification.

43 FR 6915
Published 2/17/78
Effective 5/3/78

Export and Import of Nuclear Facilities and Materials

See Part 110 Statements of Consideration.

44 FR 17479
Published 3/22/79
Effective 6/5/79

RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL, DOMESTIC LICENSING OF SOURCE MATERIAL, AND DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

Timely Notification of Discontinued Licensed Activities

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations to require licensees to notify the Commission when they decide to permanently discontinue all activities involving materials authorized under a license. This will allow NRC to terminate the license in an orderly and timely manner.

EFFECTIVE DATE: June 5, 1979.

NOTE.—The Nuclear Regulatory Commission has submitted this rule to the Comptroller General for review under the Federal Reports Act, as amended, 44 U.S.C. 3512. The date on which the rule becomes effective, unless advised to the contrary, accordingly reflects inclusion of the 45 day period which that statute allows for this review (44 U.S.C. 3512(c)(2)).

FOR FURTHER INFORMATION CONTACT:

Edward Podolak, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, phone 301-443-5860.

SUPPLEMENTARY INFORMATION: NRC issues licenses for the use of byproduct, source, and special nuclear materials[1] under 10 CFR Parts 30, 40 and 70 respectively. The usual term for these licenses is five years. At five year intervals the licensee must submit an application for renewal of the license. If the application is found satisfactory after review by NRC, the license can be renewed for another five year term.

Under the present system, NRC sometimes does not discover that a licensee has discontinued a licensed program, and perhaps even vacated the premises, until an inspection or the end of the five year license term. The NRC needs to communicate with the licensees, on a timely basis, regarding disposition of the licensed material and cleanup of the facility.

In order to remedy this, on July 27, 1978, the NRC published for 45-days public comment proposed amendments (43 FR 32431) to Parts 30, 40 and 70 that would require licensees to notify NRC when they decide to permanently discontinue all activities involving materials authorized under a license. The FEDERAL REGISTER notice explained that this means all activities authorized under a license identified by a unique NRC license number and that notification is not required if only a part of a program is to be discontinued or if it is expected that a program will be reinstated before the license expires. For example, if an academic institution has several licenses and decides to permanently discontinue all activities authorized under one license, say a Part 35 medical program, the licensee will have to notify NRC. If the institution decides to discontinue that medical program, but believes it may reinstate the program before the license expires, notification to NRC will not be necessary. If the institution decides to discontinue a portion, but not all of the activities authorized under that Part 35 medical license, notification to NRC will not be necessary.

Copies of the proposed rule were sent to all NRC Parts 30, 40 and 70 licensees. Thirty-one comment letters were received. Ninteen commenters favored the proposal without qualification. Four commenters favored the proposal but suggested minor changes in the wording of the rule. Seven commenters objected to the proposal. The final rule is identical to the proposed rule except for removing the gender specific pronoun "he".

DISCUSSION OF COMMENTS

Three commenters objected to the proposed rule because of the paperwork burden.

The Commission believes that the time and expense of notifying NRC about a decision to discontinue a licensed program is minimal. Further, the Commission believes that beginning a dialogue with the licensee on a timely basis will save both parties the unnecessary expense of last minute or even after-the-fact decommissioning problems.

Two commenters objected to the proposed rule because of their concern about an individual licensee being unable to notify the NRC due to illness or death. One of these commenters questioned if a penalty would apply under these circumstances.

The number of individual licensees is small and they are usually medically-oriented so that the types of materials authorized involve small quantities of short-lived radioisotopes which would not present a long-term contamination problem. Penalties are not usually assessed for failure to notify NRC unless this failure results in a significant health hazard or threat to the common defense and security. The Commission does not believe that the possibility or consequence of a failure to notify NRC because of illness or death of a licensee warrants abandoning the rule.

One commenter suggested that a simple questionnaire regarding the status of each license would suffice.

The Commission believes that the cost of periodic questionnaires would far exceed the cost of the notification requirement. If a questionnaire is perceived as a nuisance, compliance would be low and the cost of NRC followup would be high.

One commenter suggested that the Commission encourage licensees to notify NRC by offering a prorated return of the license fee.

A prorated return of the license fee is not possible under the new fee-for-service system. Licensees are now charged separately for the cost of reviewing license applications, the cost of reviewing license amendment applications and the cost of inspections. Therefore, there is no unused portion of the application fee to refund to a licensee who decides to discontinue a program.

FINAL RULE

In accordance with §§ 30.6, 40.5 and 70.5, the written notification that will be required under these amendments should be addressed to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 or may be delivered in person to the Commission's offices at 1717 H Street, NW., Washington, DC; or 7910 Eastern Avenue, Silver Spring, MD.

Under the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and Sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Parts 30, 40 and 70, are published as a document subject to codification.

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[1] The term byproduct material means (1) any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material, and (2) the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content. The term source material means (1) uranium, thorium, or any combination thereof, in any physical or chemical form, or (2) ores which contain by weight one-twentieth of one percent (0.05 percent) or more of (i) uranium, (ii) thorium, or (iii) any combination thereof. Source material does not include special nuclear material. Special nuclear material means (1) plutonium, uranium 233, uranium enriched in the isotope 233 or in the isotope 235, or (2) any material artificially enriched by any of the foregoing, but does not include source material.

45FR14199
Published 3/5/80
Effective 3/5/80

Minor and Clarifying Amendments

See Part 1 Statements of Consideration

45 FR 18905
Published 3/24/80
Effective 3/24/80

Deletion of Reference to Panama Canal Zone; Minor Amendments

See Part 4 Statements of Consideration.

45 FR 41393
Published 6/19/80
Effective 9/2/80

10 CFR Parts 30 and 35

Testing of Radioisotope Generators

AGENCY: Nuclear Regulatory Commission (NRC).

ACTION: Final rule.

SUMMARY: Certain Nuclear Regulatory Commission (NRC) medical licensees are authorized to prepare radioactive drugs from radioisotope generators. NRC is requiring licensees to test these radioactive drugs for a contaminant called molybdenum-99. NRC is also imposing maximum limits for molybdenum-99 in these radioactive drugs. Following a report from an NRC medical licensee, a joint NRC/FDA investigation revealed the possibility of greater than normal quantities of molybdenum-99 in technetium-99m (Tc-99m) generator eluate. The presence of molybdenum-99 serves no diagnostic purpose. Therefore, the radiation exposure from the administration of greater than normal amounts of molybdenum-99 is unnecessary to the patient.

EFFECTIVE DATE: September 2, 1980.

Note.—NRC has submitted this rule to the Comptroller General for review under the Federal Reports Act, as amended, 44 U.S.C. 3512. The date on which the rule becomes effective reflects inclusion of the 45-day period that the statute allows for this review (44 U.S.C. 3512(c)(2)).

FOR FURTHER INFORMATION CONTACT: Edward Podolak, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (Telephone: 301–443–5860).

SUPPLEMENTARY INFORMATION: In diagnostic nuclear medicine, the most widely used radioactive drug is technetium-99m (Tc-99m) which has a radioactive half-life of 6 hours. Many hospitals and nuclear pharmacies obtain their Tc-99m by purchasing a radionuclide generator from a radioactive drug manufacturer and eluting the generator.

The radioisotope generator is a shielded device that is often called a molybdenum generator or molybdenum "cow" because molybdenum-99 (Mo-99), the parent of Tc-99m, is contained within the generator. The Mo-99 is adsorbed on an alumina column which is arranged so that sterile saline solution can be fed through the column to wash out, or elute, only the daughter radioisotope, Tc-99m. The parent, Mo-99, has a longer half-life than the daughter, Tc-99m, and the parent continuously decays to form the daughter radioisotope, which is eluted when needed. The generator is usually eluted, or "milked," every 24 hours and replaced with a new generator once a week because the parent, Mo-99, has decayed below useful levels. If the Mo-99 is improperly loaded on the alumina column or loaded on an alumina column that is defective (e.g., improper packing could cause "channeling" of the Mo-99), the Mo-99 will "break through" the column and contaminate the radioactive drug.

The United States Pharmacopeia (USP) XIX, which is recognized by the Food and Drug Administration (FDA) and the pharmaceutical industry as the basic standard for drug strength, quality and purity, has upper limits for the presence of Mo-99 in Tc-99m radioactive drugs. These limits apply to molybdenum generator manufacturers and each generator's labeling includes methods or references methods for quantifying the amount of Mo-99 in Tc-99m. This is usually called a molybdenum breakthrough test.

Molybdenum breakthrough testing by the generator user has always been considered a good laboratory practice or a good quality control measure. In a section describing molybdenum breakthrough testing, the Bureau of Radiological Health (FDA) *"Workshop Manual on Radiopharmaceutical Quality Assurance"* (July 1978) states: "Thus, it is important that testing for Mo-99 be performed routinely."

Until 1975, all NRC medical licenses authorizing the use of generators included a license condition requiring molybdenum breakthrough testing. A provision in the new § 35.14 group medical licensing regulations, adopted in 1975, ultimately had the effect of dropping this license condition. Section 35.14(b)(4) requires licensees to follow the generator labeling or package inserts which, in 1975, included methods for molybdenum breakthrough testing. Over the intervening years, generator labeling has become ambiguous on molybdenum breakthrough testing. Some package inserts imply that the users *should* do it, others imply that the users *are* doing it, and still others *recommend* that the users do it. Thus, there are no uniform requirements in NRC licenses or regulations or in connection with the generator labeling for the performance of tests to determine the amount of Mo-99 in Tc-99m radioactive drugs before administration to patients.

Following a report from an NRC medical licensee, a joint NRC/FDA investigation in March 1979 revealed the possibility of greater than normal quantities of Mo-99 in Tc-99m generator eluate. The presence of molybdenum-99 serves no diagnostic purpose. Therefore, the radiation exposure resulting from the administration of greater than normal amounts of Mo-99 is unnecessary radiation exposure to patients. It could result in a radiation dose to a critical organ of one or more rems. There are several thousand generators shipped weekly, with each generator accounting for up to 50 patient dosages per day. If a problem develops in the manufacture, shipping, handling or elution of these generators that results in molybdenum breakthrough in excess of the *USP* XIX limits, there is a potential for unnecessary radiation exposure of patients.

In view of this, on March 12, 1979, NRC's Office of Nuclear Materials Safety and Safeguards issued an order requiring medical licensees to perform molybdenum breakthrough testing on each elution of Tc-99m from a generator and also prohibiting licensees from administering any Tc-99m radioactive drugs that exceed the *USP* XIX limits for Mo-99 contamination. On June 6, 1979, the Commission published in the **Federal Register** (44 FR 32394) a proposed rule that contained the essentials of that order. The March 12, 1979, order to licensees requiring molybdenum breakthrough testing remained in effect. That order is hereby rescinded by the terms of this final rule when it becomes effective.

The comment period for the proposed rule expired on August 6, 1979. Three comments were received. Two commenters favored the proposed rule. One of these commenters suggested a minor word change to clarify that the required test applies only to Mo-99/Tc-99m generators. This change was adopted in the final rule. One commenter, while agreeing that molybdenum breakthrough testing was necessary, suggested that the FDA change the generator labeling to mandate the test. The NRC believes that an NRC requirement for molybdenum breakthrough testing is more direct and effective than an FDA labeling change. FDA does not impose requirements on users of radioactive drugs through the product labeling.

The final rule covers three types of NRC medical licenses: (1) the nuclear pharmacy license, (2) the broad medical license and (3) the group medical license. Of these three types of medical licensees, the rule applies only to those who actually elute the radioisotope generators and does not apply to those who purchase prepared Tc-99m radioactive drugs from a radiopharmaceutical manufacturer or nuclear pharmacy. The manufacturer that sells prepared Tc-99m radiopharmaceuticals is covered by FDA requirements for molybdenum breakthrough testing. As noted above, nuclear pharmacies are covered by the rule.

In summary, § 35.14(b)(4) requires the group medical licensees to perform molybdenum breakthrough tests if they use generators. Section 30.34(g) requires nuclear pharmacy licensees and broad medical licensees to perform the same molybdenum breakthrough tests if they use generators.

Under the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Parts 30 and 35 are published as a document subject to codification.

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45 FR 65521
Published 10/3/80
Effective 11/17/80 *

10 CFR Parts, 30, 40, 70, and 150

Uranium Mill Licensing Requirements

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rules.

SUMMARY: The U.S. Nuclear Regulatory Commission is amending its regulations to specify licensing requirements for uranium and thorium milling activities, including tailings and wastes generated from these activities. The amendments to Parts 40 and 150 take into account the conclusions reached in a final generic environmental impact statement on uranium milling [1] and the requirements mandated in the Uranium Mill Tailings Radiation Control Act of 1978, as amended, public comments received on a draft generic environmental impact statement on uranium milling,[2] and public comments received on proposed rules published in the Federal Register. The amendments to 10 CFR Part 40 specify technical, surety, ownership, and long term care criteria for the management and final disposition of mill tailings. The amendments to 10 CFR Parts 30 and 70 are for consistency to require the completion of an environmental review by the NRC prior to the commencement of construction of certain other types of nuclear plants, such as uranium hexafluoride conversion plants or uranium processing and fuel fabrication plants. The amendments to 10 CFR Part 150 enumerate the authorities reserved to the Commission in Agreement States under the provisions of the Uranium Mill Tailings Radiation Control Act, and specify requirements for Agreement States to implement this Act.

EFFECTIVE DATE: November 17, 1980.

Note.—The NRC has submitted this rule to the Comptroller General for such reviews as may be appropriate under the Federal Reports Act, as amended, 44 U.S.C. 3512. The date on which the reporting and recordkeeping requirements of this rule become effective, unless advised to the contrary, accordingly reflects inclusion of the 45 day period which that statute allows for such review (44 U.S.C. 3512(c)(2))

FOR FURTHER INFORMATION CONTACT: Mr. Don F. Harmon, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (phone 301–443–5910).

SUPPLEMENTARY INFORMATION:

I. Introduction

In November 1978, the U.S. Congress enacted the Uranium Mill Tailings Radiation Control Act (UMTRCA). This Act provides a program to regulate mill tailings during uranium or thorium oreprocessing at active mill operations and after termination of operations to stabilize and control tailings in a safe and environmentally sound manner and to minimize or eliminate radiation health hazards to the public. In April 1979, the NRC published (44 FR 24963) for comment a draft generic environmental impact statement (GEIS) on uranium milling that assessed the potential environmental impacts of uranium milling operations, including the management of uranium mill tailings. The NRC wished to provide an opportunity for public participation in decisions concerning any proposed changes in NRC regulations based on that assessment.

On August 24, 1979, the Commission published in the Federal Register effective (44 FR 50012) and proposed (44 FR 50015) amendments to its regulations to implement the requirements of the UMTRCA and the conclusions reached in the draft GEIS on uranium milling. In October, 1979, the NRC staff held public hearings in Denver, Colorado, and Albuquerque, New Mexico, to obtain additional public input on the proposed rule changes and the draft GEIS.

The August 24, Federal Register notice indicated certain of the effective rules were to: (1) govern the Commission's licensing of byproduct material (i.e., uranium mill tailings) in Agreement States; (2) provide for a general license authorizing possession of uranium mill tailings by certain persons in Agreement States to prevent existing milling operations from being in technical violation of the Atomic Energy Act; and (3) specify that individuals in Agreement States were not exempt from Commission licensing requirements governing uranium mill tailings. Legislation was enacted on November 9, 1979 (Pub. L. 96–106) to provide clarification to Sections 204(h) and 204(e) of the UMTRCA. This legislation provided that the Commission has no direct licensing authority over byproduct material licensed by Agreement States at least until November 8, 1981. Accordingly, to conform to the requirements of Pub. L. 96–106, the Commission revoked the foregoing effective rules in a Federal Register notice published February 26, 1980 (45 FR 12377).

II. Public Response to Draft GEIS and Proposed Rules

The Commission received ninety-nine submittals in response to the request for comments on the draft GEIS and the August 24 Federal Register notice. These documents were from private individuals, uranium milling companies, trade associations, state and Federal agencies, and conservation and public interest groups. In addition, about 50 individuals, representing views of the same spectrum of groups and individuals, presented statements at the Denver and Albuquerque public hearings. The NRC staff has

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*Effective date amended 45 FR 79409
See Statements of Consideration 12/1/80

[1] Copies of the final generic environmental impact statement on uranium milling (NUREG–0706) are available for public inspection and copying at the U.S. Nuclear Regulatory Commission's Public Document Room, 1717 H St NW., Washington, D.C. 20555. Copies also available from GPO Sales Program, Division of Technical Information and Document Control, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 and the National Technical Information Service, Springfield, Virginia 22161.

[2] The draft statement (NUREG–0511) was published in April 1979 (44 FR 24963).

systematically reviewed all comments received and the transcripts of the statements presented at the public hearing and has identified approximately 1500 substantive comments on the draft GEIS and proposed rule changes.

After careful consideration of all comments, the NRC staff has prepared a final generic environmental impact statement on uranium milling and the Commission has adopted the rules supported by this document. These rules are identified and discussed below. In preparing the final GEIS, the NRC has included the latest available nuclear power and uranium milling projections obtained from the U.S. Department of Energy and has completely reviewed treatment of the following: (1) potential individual and population exposures to radioactive materials from milling activities; (2) potential health effects resulting from these exposures; (3) costs for various management and disposal alternatives; and (4) a cost benefit analysis of the effective rule changes. It also contains a new Appendix A which provides a discussion of each of the specific substantive public comments. The summary of the final GEIS provides, among other things, a general discussion of what are believed to be the major public concerns and issues raised in public comments. Appendix A and the summary of the final GEIS also contain a more detailed discussion of the significant changes appearing in the final rule changes set forth below.

Since all substantive public comments are addressed in detail in Appendix A of the final GEIS and since it is impracticable to provide here a complete summary discussion of all the complex issues raised in public comments, only those issues which the NRC staff believes cover major public concerns are discussed below.

The Commission is fully aware that Atomic Safety and Licensing Appeal Boards are now considering, in individual adjudicatory licensing proceedings and pursuant to Commission direction, issues pertaining to the environmental effects of radon releases associated with the mining and milling of uranium. It is also aware that some of the issues being adjudicated in those proceedings overlap some of the subjects which are discussed in the GEIS.

Notwithstanding its issuance at this time of a final rule imposing licensing requirements for uranium mills (including the disposal of the tailings generated in the milling process), the Commission intends that the Appeal Boards proceed to decision on all issues pending before them in the radon release proceedings. In so doing, the Appeal Boards are to base their decision on the adjudicatory record of those proceedings. To the extent, if any, that, in the judgment of the Appeal Boards, the adjudicatory record may call for findings different from those contained in the GEIS and reflected in the final rule, the Appeal Boards will be free both to make and to implement such findings in their decision.

The Appeal Boards' decision will, of course, be subject to review by the Commission either on petition of a party to the proceedings or on its own initiative. In the course of any such review, the Commission will have the opportunity to examine any findings made by the Appeal Boards which are or might be inconsistent with those GEIS findings underlying the final rule which is now being adopted. Depending upon its resolution of the inconsistency, the Commission may then either (1) reverse or modify the Appeal Boards' decision; or (2) amend the final rule to bring it into conformity with that decision.

In determining to promulgate the final rule at this time despite the possible need for its revision following the conclusion of the adjudicatory proceedings concerned with radon releases, the Commission has heavily influenced by the consideration that prompt issuance of the rule is imperative to ensure that, by November 8, 1981, Agreement States will be able to take that action necessary to bring their byproduct and source material licensing programs into compliance with Section 274o of the Atomic Energy Act of 1954, as amended. In this connection, although not prejudging the outcome of the pending adjudication, the Commission believes that the GEIS provides a sufficient basis for the issuance of a final rule without further delay, subject to later possible amendment.

III. Major Issues Addressed in Public Comments

Timing of Regulations

A number of commenters took the position that there is no great sense of urgency for regulations on uranium mill tailings management and mill operations. However, each year new mills are proposed and many millions of tons of tailings are generated at existing mills. As new mills are constructed and more tailings are generated, the options for dealing with tailings disposal become fewer. It is critically important that the siting and design criteria of the regulations be implemented for new facilities so that mistakes of the past are not repeated. In addition, and perhaps even more important, radioactive releases from existing mills constitute the largest potential routine releases from the nuclear fuel cycle. Therefore, it is absolutely essential that regulations, which assure that action is taken to protect the public health and safety, are promulgated promptly.

The NRC intends to promulgate the regulations recognizing that research, much of its sponsored by NRC, is still being conducted in many areas covered in the rules. The regulations are established on the basis of knowledge obtained from licensing experience and research conducted to date. Research sponsored by NRC, DOE, the industry, and others will continue, and changes can be made to regulations if research indicates that changes are necessary or appropriate. However, the NRC considers it likely that information from this research will provide a basis for supplementing the broad criteria of the regulations with more specific regulatory guidance rather than a change in the overall objective of any criterion. In any case, the NRC considers it urgent to issue the regulations now, but expects to review them from time to time to assess whether any changes are warranted.

A number of commenters indicated that their interpretation of the UMTRCA was that EPA was required to develop standards before NRC promulgated its rules. Section 275 of the Atomic Energy Act, as amended by the Uranium Mill Tailings Radiation Control Act of 1978 (UMTRCA), requires EPA to issue environmental and health standards for uranium mill tailings. However, an analysis of the Mill Tailings Act and its legislative history indicates that the Commission not only has the authority but also the immediate duty to insure that the management of uranium mill tailings is carried out in a manner that will protect the public health and safety and the environment.

Although NRC could have delayed developing regulations until EPA issued standards, that would have left unfinished the program to develop rules which NRC has been working on for nearly three years. In addition, a delay would have made it difficult, if not impossible, for the Agreement States to issue equivalent standards as required. It is clear from the UMTRCA that NRC's minimum Federal standards must be promulgated as promptly as possible so that the Agreement States will be able to have equivalent regulations in place by November 8, 1981.

NRC is aware that its regulations must be compatible with the generally applicable standards established by EPA; therefore, the NRC staff has been and will continue to coordinate closely with EPA on this matter. NRC regulations will be revised, if required, when EPA standards are issued.

Application of Regulations at Existing Sites

A number of commenters stated that tailings disposal criteria should not be applied too strictly at existing sites. Other commenters were concerned that regulations should be more specific about how the criteria will apply to these sites. In the latter case, the concern was that remedial action must be taken at existing sites where criteria are not met.

Regulations were developed recognizing that it may not be practicable to provide the same measures of conservation at existing sites as can be done at new sites where alternatives are not limited. Certain requirements in the regulations represent minimum levels of protection of public health, safety, and the environment. These requirements can and must be met in all cases. For example, requirements for minimum tailings cover, erosion protection, financial surety provisions, and the broad requirement that no ongoing active maintenance be needed to preserve the tailings isolation are mandatory in all cases. It would not be possible, on the other hand, to line the bottom of an existing tailings impoundment. Also, objectives concerning remoteness from people, providing below-grade burial, and transferring ownership of sites, may not be met to the same degree at an existing site as at a new site.

At some point, a determination, based on how a site measures up against all of the criteria, must be made as to whether the tailings should be relocated from an existing to a new site, or that, while it would be acceptable for existing tailings to be stabilized in place, tailings generated in the future should be deposited at a new location. The conditions which would lead to this determination cannot be spelled out in generic fashion in regulations because they are so variable. In any event, a full evaluation of tailings disposal and alternative sites must be completed at each milling operation and final plans formulated through a public decision making process such as is provided for by NEPA and UMTRCA.

Form of Regulations

Some commenters stated that the regulations are too specific and inflexible and, thus, restrict operators from finding new and cost effective ways to meet broad goals at any particular site. For example, some felt that regulations should only state that groundwater quality must be protected and not be specific about methods of accomplishing this. On the other hand, others considered regulations should be more specific on certain issues. For example, some wanted regulations to specify, in numerical terms, allowable hydrologic, topographic and drainage conditions.

The NRC has developed regulations mindful of the need to avoid being overly restrictive. The NRC's experiences over the past several years, working with interim tailings management performance objectives similar in nature to the criteria contained in the following rules, has been that the industry can develop many innovative ways of achieving broad goals. Also, the NRC recognizes, as stated throughout the draft and final generic impact statements, that the problem of tailings management is highly site specific. The precise details of a program can be worked out only when unique conditions of a site are known. For example, the extent of potential groundwater impacts, or the erosion potential of a tailings disposal program depends critically upon topographic, geologic, hydrologic, and meteorologic conditions which can vary significantly from site to site. The rules have been developed with flexibility to reflect this fact.

On the other hand, the NRC has attempted to make the rules as specific as possible within the constraints noted above. This is necessary for the following reasons: (1) for fairness to applicants and mill operations in that it reduces uncertainty about what requirements are and thus allows them to plan their operations reasonably; (2) to assure consistency in application of requirements which would not occur if the rules are too broad; and (3) to ensure that a minimum level of protection is provided where there are known problems or large uncertainties about potential problems. For example, a minimum cover thickness is specified and criteria for surface stabilization are established to account for known problems which potentially threaten long term tailings cover performance.

Scope of the GEIS

There were numerous comments criticizing the "model mill" approach taken by the NRC in analyzing potential environmental impacts. More specifically, commenters pointed to various aspects of the mill that were not representative of a certain, real mill, or criticized lack of analysis of certain conditions or impacts which have arisen in specific cases.

However, as repeatedly noted in the GEIS, the factors which determine the extent of impacts from milling operations are extemely site specific. All of the variations which exist with regard to these factors could in no way be taken into account explicitly in the GEIS. The model mill and model site were described, and subsequent analysis of them was carried out, in enough detail to: (1) identify the major issues or impacts of concern with uranium milling and tailings disposal, and (2) characterize their nature and extent. Costs and benefits of alternatives for mitigating these impacts were evaluated. The product of these analyses is as new regulation, cast primarily in the form of performance objectives which recognizes that the precise methods or combination of methods of impact mitigation can only be worked out on a case-by-case basis where all unique, site specific conditions can be accounted for.

The NRC did a comprehensive review of existing conditions in all of the current uranium milling regions in developing the model mill and site, and in performing the analysis of the GEIS in general. This was done to assure that the *major* differences in conditions from those assumed for the GEIS models were known in performing the analysis. Where these differences are important in terms of specific points in regulations, such as radon flux limits, the full range of variability in conditions has been explictly evaluated to assure it is reasonable to apply the regulations at all sites.

Because major decisions concerning siting and design remain to be made for each case once needed site-specific information is available, and because of the significant and longevity of the potential hazards associated with uranium mill tailings, a comprehensive environmental assessment of each mill and tailings waste disposal operation and alternatives must be conducted. It is also essential that this alternative assessment be conducted so there is opportunity for full public scrutiny of the decision being made. NRC regulations, 10 CFR 51, assures that this is done. UMTRCA (Pub. L. 95–604) establishes a requirement that Agreement States do the same. The regulation has been designed to assure these assessments are supported by full environmental assessments and investigation of site conditions by applicants and mill operators.

In no way is the GEIS a substitute for site-specific environmental assessments.

Siting of Mills

Many commenters expressed the need to be more specific and stringent concerning siting requirements. For example, some wanted a specific definition of what would be accepted as a "remote" site, a term used in the proposed rules.

However, the matter of tailings disposal is not a one-dimensional problem; that is, several factors must be considered simultaneously. Too much specificity would be imprudent since, for example, establishing a minimum distance to population centers might unduly constrain efforts to deal with other concerns such as protecting groundwater by avoiding aquifers of

high quality. The rules have been revised from their proposed form to clarify that the process of site selection involves optimization to the maximum extent practicable of the following general site qualities:

- remoteness from populated areas;
- hydrogeologic and other environmental conditions conducive to continued immobilization and isolation of containments from usable groundwater sources; and
- limited potential for erosion, disruption, and dispersion by natural forces.

Tradeoffs will inevitably be required in this process. In any event, siting is of paramount importance in developing optimum tailings disposal programs. The problem of tailings disposal cannot be approached with the attitude that inadequate siting features can be compensated for by design. For this reason, the rules state, as originally proposed, that in the selection of disposal sites, primary emphasis shall be given to isolation of tailings or wastes, a matter having long term impacts, as opposed to considerations of short term convenience or benefits, such as minimization of transportation or land acquisition costs.

Radon Control and Tailings Cover Requirements

Many commenters stated that the requirements for radon control should be based upon a fully quantified, incremental cost-benefit evaluation. However, the NRC staff reached a conclusion in the draft GEIS that attempting to establish tailings cover requirements on the basis of a quantified, incremental cost-benefit evaluation is unreasonable and, indeed, may be misleading.

In response to these comments, however, the NRC staff reexamined and expanded its evaluation of the strictly monetized, incremental cost-benefit methodology. Conclusions expressed in the draft statement concerning the impracticability and inappropriateness of attempting to set a radon exhalation limit solely by this method were fully reconfirmed. This is discussed more fully in Section 5.2.2 of the Summary of the final GEIS. Given the long term nature of the mill tailings hazards, and the complexity and uncertainty associated with predicting actual levels of radon emissions and impacts over the long term, it is concluded that the problem of determining tailings containment requirements cannot be reduced to the purely mathematical formulations required for the quantitative cost-benefit optimization methodology. The mathematical process grossly oversimplifies the problem and, thus, while it appears to offer a "rational approach" to decisionmaking, it can be misleading and quite arbitrary.

One of the obvious problems with this methodology is that arguments can easily be made for virtually opposite positions (little or no control, versus absolute control or radon releases) merely by measuring potential health impacts over short or long time periods. In fact, commenters did this. The monetary worth of averting a health effect ("life loss" or "life shortening" due to cancer) is another highly subjective factor which can vary widely and, thus, make more uncertain the level of control which should be required. While arbitrary decisions might be made concerning these factors, there is no practicable way to correlate long term containment performance uniquely with costs.

The NRC staff established the proposed final tailings radon flux limit based upon an evaluation of a wide range of public health and cost factors, and the variability of site specific conditions. More specifically, these factors included evaluation of alternative radon release limits in terms of: costs for applying a final tailings cover under a full range of conditions that will occur with varying ore grades, impoundment sizes and shapes, cover material types and so on; impacts on maximum exposed individuals as they compare with existing radiation protection standards; total population exposures as they compare with population exposures from natural and technologically enhanced radon releases, both short and long term; and, radon fluxes that occur from natural soils.

In consideration of these perspectives and the problems with monetized cost-benefit evaluations, it was determined that the most reasonable residual radon emission limit would be one that would assure that tailings disposal sites are eventually returned to conditions which are reasonably near those of the surrounding environs. The radon flux limit assures that radon exhalation rates will be within the range of flux rates occurring naturally from nearby soils.

Period of Long Term Concern

Many commenters stated that tailings disposal should be viewed as a problem spanning eventually an infinite period of time, and the total number of potential health effects resulting from radon releases should be viewed in absolute terms. By integrating health effects over such periods of time, the number of calculated health effects is extremely large and, on the basis of this, commenters urged that advanced modes of tailings disposal are warranted to provide complete or improved isolation of tailings. On the other hand, some stated that, because of the vast uncertainties involved, and the potential for development of a cure for cancer, a much shorter period such as 100 years is appropriate for evaluating the need and cost-effectiveness of controls. On this basis, much less stringent controls are urged.

The NRC has evaluated this problem and developed regulations considering the inescapable fact that the tailings will, in fact, remain hazardous for extremely long periods of time, hundreds of thousands of years. Viewing this matter as one of only short term significance because of the uncertainties involved with the long term or on the speculation that there may be a cure for cancer is unrealistic and not responsible. On the other hand, attempting to provide absolute assurances that the tailings, which are very large volume, low-specific activity wastes, will remain completely isolated for infinite time frames is impracticable and inappropriate when the potential impacts of other naturally occurring and technologically enhanced, persistent radon sources are considered.

The general conclusions about the various tailings disposal modes are summarized in Summary Section 5.2.1 and Section 12.3.3 of the final GEIS. The tailings siting and design features specified in the regulations are intended to provide a degree of isolation which is consistent with the reality that the tailings present long term hazards. These measures are those identified to be needed to account for potential failure mechanisms which can occur in the very long term. The features which are being incorporated into tailings disposal programs under the regulations are similar to those of landforms which have been known to be stable for extremely long periods of time. For example, elimination of embankment slopes by below grade burial or use of rock covering on very gentle slopes will make sites stable landforms. The latter will duplicate conditions such as those existing in alluvial deposits in Death Valley which have been stable for 20,000 years because of the "armoring" provided them by course rock and gravel "desert pavements." Minimum requirements on cover thickness have been specified with the knowledge that covers performance can be degraded in numerous ways.

In general, the condition of tailings disposal sites should be virtually the same as those in surrounding environs and should remain so without active care and maintenance. Advanced tailings disposal modes such as fixation or nitric acid leaching may offer potentially improved isolation, but the improvement over what are considered adequate programs is uncertain while the costs are excessively high and other new problems are encountered with such technologies.

Groundwater Protection

A number of separate issues were raised concerning the matter of tailings impoundment seepage and groundwater protection.

Some commenters stated that in addition to requiring control of seepage, the regulations should clearly specify that groundwater uses must be protected as there will inevitably be some seepage occurring. The NRC's intent in the proposed regulations was to protect current and potential groundwater uses and the final regulations have been drafted to explicitly state this. That is, where an aquifer below a site is initially of drinking water quality, it shall remain so during and after operations.

Others questioned whether continued seepage from impoundment would not be a problem over the very long term. Because uranium milling in the United States is conducted in semi-arid regions and evaporation rates are frequently far in excess of rainfall rates, it is not expected that seepage will be along-term problem. There is concern about providing good seepage control primarily during the operational period when hundreds of tons of waste solutions are generated daily at an average mill. After the impoundments dry, there will be virtually no driving force for seepage. There is good reason to expect that there is, in general, little recharge of aquifers in interfluvial zones in the semi-arid milling regions, if there is any at all. It is for this reason that the NRC has accepted use of synthetic liners, the likely long term stability of which is questionable at best. Many commenters stated that the matter of groundwater protection should only be presented as a broad performance objective, and that specific methods of control should not be identified in the regulations. The concern is that the regulations will be too restrictive. In general, the NRC has identified seepage control as the most effective and positive way of protecting groundwater; methods of seepage control are identified in the regulation, but flexibility is provided to select the most appropriate ones in a case-by-case basis. (See response to the comment on the form of regulations above.)

Some commenters noted that spread of seepage contamination can occur rapidly by fractures, buried channels and other zones of high hydraulic conductivity, and stated that the GEIS and regulations should recognize this. Experience has indeed shown this concern to be valid. This has been a matter which routinely receives scrutiny by the NRC in licensing reviews and uncertainty about the existence of such discontinuous features at a site are in great measure, the reason for the NRC's conclusion that seepage prevention is the most appropriate approach to take in groundwater protection. Furthermore, the regulation has been revised to specify more clearly what site information is needed to provide an adequate understanding of hydrologic and geologic conditions which will control seepage and contaminant transport.

Finally, some stated that any area which overlies an aquifer of potential use must be avoided. As discussed above in discussions of the issue of siting, the NRC has revised the regulations to clearly indicate that one of the few most important matters which determine what is an acceptable site is the matter of groundwater protection (see the response to the siting issue above). However, a universal prohibition on siting near aquifers is inappropriate given constraints imposed in meeting other major objectives and given the seepage control measures which can be taken to effectively assure groundwater use is preserved.

Cost Estimates

Several commenters considered the cost estimates of the alternative tailings management programs presented in the draft generic environmental impact statement to be underestimated. In estimating costs in the draft, the NRC considered cost information submitted by the industry in connection with mill licensing cases, obtained quotes from vendors and suppliers, and gathered information from current literature on earthmoving and construction costs. Alternatives were clearly defined as combinations of separate unit operations, the cost of each being stated as a range. Single unit costs were selected from within the range to arrive at total costs. These total costs were consistent with those reported by the industry in actual NRC licensing cases. Where costs were particularly sensitive to assumptions made in defining alternatives, the effects of variations in assumptions on costs were clearly stated.

The NRC has reevaluated costs in the final GEIS. In doing so, the NRC consulted other sources in addition to those consulted in preparing the draft GEIS. In general, the NRC found that costs increased by an amount attributable to inflation since the cost estimates were made for the draft GEIS document in 1978.

Environmental Impacts of Obtaining Reclamation Cover Material

Several commenters noted that considerable amounts of cover material would be required to perform final reclamation, that in some cases such material would have to be strip-mined in otherwise undisturbed areas (which would yield significant environmental impacts), and that such impacts were not addressed in the draft statement. It was further stated that this is particularly of concern at existing sites using above-grade disposal and that in some areas the depth of soil available for excavation is very limited. Under such conditions it would be necessary to excavate cover material from very large areas to obtain sufficient quantities of earth to provide reclamation in accordance with tailings cover requirements.

This final GEIS includes an assessment of the potential environmental impacts of obtaining cover material (see Section 9.3.8.4). The assessment includes analysis of what is considered by the NRC to be a potential worst-case situation wherein: (1) cover material must be obtained by strip-mining otherwise undisturbed terrain; (2) cover material must be hauled to the site from a distance of 10 miles (16 km); and (3) the average depth of soil available for excavation in the borrow area is only about 1 meter (not including about 0.5 m of topsoil which must be stripped, stored, and reapplied to revegetate the borrow area). These conditions are considered to be very conservative assumptions. Overburden or mine waste produced during local mining operations may well be available, and if so, would be suitable material provided only that it did not contain excessive radioactivity. To the extent that overburden or mine waste could be used, requirements for undisturbed soil materials would be reduced. Also, the NRC believes that adequate cover materials can be found within distances much less than 10 miles (there are over 300 sq. miles of area within a radius of 10 miles from any point), if not on the mill site itself. Furthermore, the depth of soil which may be excavated and removed will likely be much greater than 1 meter. Even in the rugged and rocky terrain of the Grants, New Mexico area excavation depths of 15 m (60 ft.) or more are feasible.

With respect to environmental impacts, even under the very conservative assumptions described above, environmental impacts are limited; they are, at worst, comparable to those arising from mill construction with respect to air quality, land use, biota, water resources, and on the community. Given that reclamation of the borrow area will include revegetation to a natural condition, all impacts would be temporary except for the permanent alteration of topography and the irretrievable commitment of fuel burned by the trucks used to haul the cover material to the tailings disposal site. The NRC considers such impacts as small and insignificant in comparison to the benefits obtained by assuring long term physical isolation of the buried tailings and reduced residual radon emissions.

Financial Surety

Several commenters argued that self-insurance or third-party insurance should be considered as a surety mechanism. The basis for ruling out self-insurance is simply that such an arrangement would provide no additional assurance, other than that which would already exist through license requirements. Other commenters indicated that the required amount of surety coverage should be based on the licensee's costs for decommissioning and reclamation as opposed to contractor costs which include increased overhead and profit. With regard to the required amount of surety coverage, it seems obvious that the purpose of the surety mechanism is to protect the public from the possibility of a licensee's inability to perform the required decommissioning and reclamation and thus the only time when a surety would be collected would be in the event of default. A licensee's cost estimate would certainly be less than costs which an independent contractor would charge; therefore, inadequate protection would result if estimates based on licensee costs were permitted.

Several other commenters questioned the availability of surety bonds under the conditions described as necessary for satisfaction of the surety requirement. Although the NRC's investigation of the situation does indicate that there seems to be resistance on the part of some bonding companies to becoming involved in issuing bonds to companies subject to government regulation, the resistance appears to be the result of a misunderstanding of the requirements of the regulation. The surety mechanism covers specific decommissioning and reclamation activities committed to by operator in the license and is not a guarantee to satisfy an indefinite set of requirements which may be established 15 or 20 years in the future. Furthermore, the evidence indicates that the surety market is competitive since some bonds have been obtained by uranium recovery operators even recently. In addition, flexibility exists in terms of acceptable types of mechanisms to satisfy the surety requirement.

Another comment which was raised pertaining to the decommissioning and reclamation surety concerned the required term of the surety. As stated in the draft GEIS and the proposed rules, the term of the surety must be open-ended in order to provide the requisite high level of assurance. The NRC considered that unless the surety remained in force until decommissioning and reclamation activities covered by the arrangement were completed, there would be nothing to prevent the surety company from cancelling the arrangement if and when the financial stability of the licensee became questionable or at the end of milling operations when the assurance is most needed. Obviously, this would provide the public with totally inadequate protection. However, through further consideration and investigation, the NRC has learned that other types of arrangements may provide the same high level of assurance as an open-ended arrangement does. Therefore, provision has been made in the decommissioning and reclamation surety criterion to allow flexibility concerning the term of the arrangement, providing the same high level of assurance exists.

Long Term Funding

A number of comments were received concerning the requirement that an amount be paid to cover the costs of long term site surveillance. Some commenters indicated that the amount, the equivalent of $250,000 in 1978 dollars, was too high, others stated that it was too low, and some indicated that they considered it should correlate with the size of the disposal site. The basis for the long term fund, as established in the draft GEIS, is that something on the order of an annual site inspection to confirm the integrity of the site will be all that is necessary. However, the requirement is designed so that sufficient flexibility exists to increase the required charge, if appropriate, at certain sites if it is determined that the necessary level of surveillance and site control are significantly greater than government agency, because it is probably the only institution which would have sufficient resources, would be available to support proper action. However, transfer of certain subsurface rights may be of less importance in providing the necessary control.

Thus, although Criterion 11 requires applicants/operators to make a serious effort to acquire all interests in the land, sufficient flexibility is maintained to permit the Commission to determine that surface ownership, by itself, of a site with characteristics conducive to long term stability may be sufficient. In addition, the Commission would require appropriate notice in the public land records that the land is being used for tailings disposal and thus, would be subject to an NRC license prohibiting the disturbance of the tailings in the exercise of any other interest in the real property.

In addition, Criterion 11 makes essentially no distinction between land ownership requirements for licenses issued before or after November 8, 1981. As discussed in Sections 12.3.11 and 13.4 of the final GEIS, the NRC has concluded that surface ownership is necessary to assure ongoing surveillance, except possibly in the case of deep mine disposal. Thus, although UMTRCA directs the Commission to specifically consider the status of land ownership at existing facilities, the NRC does not consider it reasonable to expect that any licensee or site owner would be willing to accept the onerous obligation associated with a perpetual NRC license, which would be required if land ownership is not transferred. Given these circumstances, the NRC does not expect there will be a situation where waivers to surface land ownership transfer requirements will be appropriate.

Agreement State Regulation

A number of commenters indicated that the draft GEIS failed to assess the Agreement States' programs. Others inquired as to how the new requirements would be implemented in Agreement States. The amendments to the Mill Tailings Act in 1979 clarify when the new requirements become effective in Agreement States. Generally, the States are required to implement the new requirements immediately, to the extent practicable, and to establish standards by November of 1981 which are equivalent to, or more stringent than, the minimum national standards established by the Commission. Also, the UMTRCA requires Agreement States to complete independent, documented environmental assessments in assumed in the GEIS. For example, this might occur if fencing is determined to be necessary. However, the NRC considers that as long as some ongoing monitoring is appropriate, the nominal charge established by this requirement could hardly be reduced.

Other commenters indicated that they considered the long term fund charge should be designed like an insurance fund and cover any damage which may result from a catastrophic event. As discussed in Section 14.3 of the final GEIS, the staff considered an insurance fund to cover costs associated with unforeseen events such as catastrophic occurrences, but rejected this option on the basis that the likelihood of such an occurrence would be small and design against it would be impractical beyond that which is already required in terms of siting and design. As mentioned above, where there is significant uncertainty about long term performance, which might occur at an existing site where options for tailings disposal are limited, more than the minimum fee can be charged.

Government Land Ownership

A number of commenters inquired about how the land ownership requirements would be implemented, particularly with regard to existing facilities where UMTRCA explicitly allows for NRC discretion. Transfer of an unencumbered fee estate may be difficult to achieve since land ownership can be a complex matter, particularly in western states where it is not uncommon for surface rights, mineral rights (including oil and gas), and water rights to be conveyed as separate interests. The NRC is concerned that if complete and total transfer is required, land ownership considerations (i.e., the difficulty in assembling title to all interests) may significantly impact the selection of sites. If the ability to obtain title to land became a driving force in the site selection process, this would be wholly inconsistent with the fundamental conclusion of the GEIS, i.e., that physical isolation as opposed to institutional arrangements must be the primary means of long term control.

In addition to concluding that physical site characteristics conducive to long term stability are of overriding importance, the NRC considers that in most cases Government control of the surface rights is necessary (1) to control land uses at the disposal site which could lead to disruption of the tailings, and (2) in general, to assure ongoing surveillance is performed. Government control is also considered prudent so that in the unlikely event that remedial action at a disposal site is required, a connection with each licensing case. The need for such documents and public review is a major conclusion of the final GEIS. The Mill Tailings Act also requires the Commission to evaluate the equivalency of the Agreement State program by November 1981. A more comprehensive set of criteria to be used in review of Agreement State programs is being developed by the NRC and will be made publicly available. It is considered that a detailed evaluation of the Agreement State program is not appropriate in the GEIS; however, the general role of Agreement States and their relationship with NRC is discussed.

Exemption From Licensing Small Quantities of Byproduct Material

Some commenters suggested that small quantities of byproduct material connected with research and development should be exempted from licensing requirements. The NRC agrees that this would be desirable but is not, at this time, proposing rules to provide for either an exemption or general license (i.e., a license effective without the filing of applications with the Commission or the issuance of licensing documents to particular persons) covering small quantities of byproduct material. In order to exempt materials from licensing requirements or issue general licenses, the Commission must determine that the quantities of materials involved will not be harmful to the health and safety of the public and to the environment. It is the NRC's understanding that the quantities of tailings generally involved in research and development activities may be as large as a few tons. The NRC notes that a quantity such as this may, among other things, result in a buildup of unacceptable radon concentrations in improperly ventilated structures. Thus, the NRC believes that additional evaluations are necessary before it can be determined what quantities of tailings can be exempted from licensing requirements or be covered under a general license. The NRC is therefore further considering this issue and plans to publish its conclusions on this subject at a later date in order not to delay issuance of the rules identified below.

In the meantime, it will be necessary for individuals conducting research and development activities using byproduct material, as defined in 10 CFR Part 40, to obtain a specific NRC license. The NRC does not believe this should be a significant administrative or costly burden on applicants since it is anticipated minimal information will be required in license applications (i.e., provisions for (1) providing proper ventilation; (2) conducting necessary radiation safety surveys; and (3) disposal of materials to properly licensed persons). Furthermore, there are presently no fees in 10 CFR Part 170 applicable to the use of these quantities of byproduct material for research and development activities. The NRC does not plan to require fees for these licenses, at least until formal rules to 10 CFR Part 170 have been adopted. The NRC requests written comments on this matter and any additional information on specific quantities and uses to be considered for exemption or covered by a general license. The technical basis for such comments is also requested.

IV. Significant Features of Final Rules

The rules promulgated in this notice are derived from the conclusions reached in the final GEIS on uranium milling and the requirements established by the UMTRCA. The major conclusions reached in the final GEIS relative to needed rule changes, stated here in broad terms, are:

1. In selecting among alternative tailings disposal sites or judging the adequacy of existing sites, consideration should be given to specific site characteristics which will assure meeting the broad objective of isolating tailings and associated contaminants from humans and the environment without ongoing active maintenance for thousands of years.
2. The "prime option" for tailings disposal is placement below grade.
3. Where full below grade burial is not practicable and tailings must be located above grade, tailings should be placed as much below grade as is reasonably achievable.
4. Methods, such as liners or dewatering, should be employed to reduce seepage of toxic materials into groundwater to the maximum extent reasonably achievable. Any seepage which might occur must not result in the deterioration of the quality of existing affected groundwater.
5. Sufficient earth cover, but not less than 3 meters, should be placed over tailings to reduce radon exhalation from buried tailings to a calculated value of not more than $2 pCi/m^2$-sec above natural background levels. A full self-sustaining vegetative cover should be established on the earth cover or a rock cover employed to reduce to negligible amounts the potential for significant wind and water erosion of the earth cover. In arid and semi-arid regions where it is unlikely vegetation will be full and self-sustaining, rock cover stabilization is mandatory.
6. Milling operations should be conducted so that all airborne effluent releases are reduced to as low as is

reasonably achievable. To accomplish this objective, staged reclamation of tailings systems should be considered to control radon emissions and the blowing of dusts from tailings and frequent determinations of the performance of emission control devices should be made to ensure that these devices are operating at anticipated efficiencies.

7. Financial surety arrangements should be established to ensure that sufficient funds are available to cover the costs of decontamination and decommissioning the mill, mill site, and environs and for the reclamation of tailings areas.

8. Sites on which tailings are finally disposed should be controlled through ownership and custody by a government agency unless, in special cases as might occur in deep mine disposal, this is determined unnecessary.

9. Funds should be provided by each mill operator to cover the costs of long term site surveillance and any probable long term monitoring and maintenance requirements.

10. Construction of a uranium extraction facility or tailings disposal area should not commence until the NRC has completed its final environmental impact assessment required by the National Environmental Policy Act (NEPA), or an Agreement State has completed its written environmental analysis as required by UMTRCA.

The UMTRCA, among other things, specifies:

1. A revised definition of "byproduct material" to include tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content;
2. Ownership and custody requirements for byproduct material;
3. Provisions for requiring bonds, sureties, or other financial arrangements covering the decontamination, decommissioning, and reclamation of sites, structures, and equipment used in conjunction with byproduct material; and
4. Provisions governing Agreement State authority under Section 274 of the Atomic Energy Act.

The significant features of the new rules are discussed below. Several changes, as indicated in the above discussion and the Summary and Appendix A of the final GEIS, have been made in these rules to reflect public comments, to better clarify specific requirements, and, where practical, to provide flexibility.

1. Section 40.26 of Part 40 is amended to add a new paragraph (d) which specifies that the general license covering tailings at active mills expires within nine months from the effective date of this amendment unless an affected licensee has submitted an application for license renewal or amendment which includes a detailed program from meeting the technical and financial criteria contained in the new Appendix A to Part 40. The Commission considers this amendment necessary to ensure that all existing mill operators who have not already done so develop acceptable programs relating to the long term disposition of tailings at active mills in a timely manner.

2. Section 40.31 of Part 40 is amended by adding a new paragraph (g) to require applicants for mill licenses to propose written specifications relating to the operation of mills and disposition of tailings or wastes to achieve requirements and objectives set forth in a new Appendix A to 10 CFR 40. As provided by paragraph (g), applicants for mill licenses must clearly demonstrate how the requirements and objectives set forth in Appendix A have been addressed; failure to clearly demonstrate how the requirements and objectives in Appendix A have been addressed will be grounds for refusing to accept an application for a license. These requirements and objectives are discussed in the following Item #3.

3. A new Appendix A entitled, "Criteria Relating to the Operation of Mills and Disposition of Tailings or Wastes Produced by the Extraction or Concentration of Source Material From Ores Processed Primarily for their Source Material Content," is added to 10 CFR 40. As indicated in the August 24 notice, this appendix consists of four major categories: technical criteria; financial criteria; site and byproduct material ownership criteria; and long term site surveillance criteria. These criteria are, for the most part, essentially the same as those contained in the August 24 notice except that many of the terms and provisions included in the proposed criteria have been more explicitly defined and/or clarified as recommended in public comments. Also, flexibility is provided in many cases as suggested in public comments to allow achieving an optimum tailings disposal program on a site specific basis.

The detailed bases for the criteria in the new Appendix A are contained in the final GEIS. As noted above in preparing the final GEIS, the NRC has completely rechecked cost estimates for meeting the major criteria in Appendix A. Estimated costs were derived from information on costs submitted by applicants for licenses, experienced engineering consultants under NRC contracts, and other information on costs available to the NRC. The Commission believes that under these criteria tailings and wastes can be disposed of at reasonable costs in a manner that the purposes and mandates of the UMTRCA will be achieved and fulfilled, respectively. Thus, the need for ongoing active care and maintenance programs to redress degradation of the tailings isolation by natural weathering and erosion forces can be essentially eliminated. In that the technical criteria relating to the siting of mills and tailings disposal areas preclude location of tailings or milling operations in an area that could be disrupted by natural events such as flooding, these criteria will ensure that the requirements of Executive Order 11988 of May 23, 1977, concerning flood plain management are met. Therefore, as well as assuring tailings isolation, flood plains will be protected.

The new Appendix A requires all mill operators to develop and submit to the NRC definitive programs meeting the technical and financial criteria in the Appendix. These programs must be submitted with license renewals or within nine months from the effective date of the appendix, whichever occurs first.

4. Paragraphs (b) of § 40.14 and (e) of § 40.32 of 10 CFR 40 are amended to require the Director of the NRC's Office of Nuclear Material Safety and Safeguards or his designee to make a positive finding on an applicant's proposed plans as meeting the requirements and objectives in Appendix A prior to commencement of construction of a mill which produces byproduct material. This finding would be that made in the final environmental impact statement (or other environmental assessment) prepared pursuant to 10 CFR Part 51. These amendments delete paragraph (b) of § 40.14 and preclude exemptions from the requirements of §§ 40.31(f) and 40.32(e) of Part 40. They also amend paragraph (e) of § 40.32 to require the denial of applications for licenses where construction is started before the appropriate environmental appraisals are completed and documented. Construction activities are likely to result in significant and long lasting environmental impacts, the propriety of which cannot be ascertained until these environmental appraisals are completed and documented. The Commission also notes in this regard that milling results in the production of large quantities of byproduct material as tailings each year. When construction of a mill begins, including its tailings disposal area,

irrevocable commitments are made regarding tailings disposal. Given that each mill tailings pile constitutes a low-level waste burial site containing long lived radioactive materials, the Commission believes that prudence requires that specific methods of tailings disposal, mill decontamination, site reclamation, surety arrangements, and arrangements to allow for transfer of site and tailings ownership be worked out and approved before a license is granted.

The Commission further notes that similar irrevocable and/or irretrievable environmental impact and resource commitments are involved in the commencement of construction of plants and facilities in which source materials are possessed and used for the production of uranium hexafluoride and commercial waste disposal by land burial. Accordingly, the requirements of the revised paragraphs (b) of § 40.14 and (e) of § 40.32 would apply to these plants and facilities.

5. The amendments to 10 CFR 30 and 70 also relate to commencement of construction of other types of plants and facilities in which byproduct and special nuclear materials are used and possessed. The Commission believes commencement of construction of these plants and facilities may also result in irreversible and irretrievable commitments of environmental impacts and resources. Therefore, the Commission believes that it is also desirable and necessary that a final environmental impact statement or assessment be completed and documented before authorizing commencement of construction. Thus, 10 CFR 30.11(b), 10 CFR 30.33(a)(5), 10 CFR 70.14(b) and 10 CFR 70.23(a)(7) are amended to conform to the foregoing amendments to 10 CFR 40.

6. A new § 150.15a is added to 10 CFR Part 150 to enumerate certain authorities reserved to the Commission under UMTRCA. Paragraph (a) is drawn directly from sections 204(f) and 202(a) of UMTRCA. Paragraph (b) is extracted from § 83 of the Atomic Energy Act of 1954, as added by § 202(a) of UMTRCA. The language of UMTRCA and its legislative history indicate that the NRC is to make the determinations under, and establish standards pursuant to, § 83, which minimum Federal standards and determinations must, under § 204(e) of the UMTRCA, be met by the Agreement States. New §§ 150.31 and 150.32 outline requirements in the UMTRCA for Agreement State regulation of tailings or activities that produce such tailings or wastes. These new sections are taken directly from § 274o of the Atomic Energy Act, as added by § 204(c) of the UMTRCA.

Under the provisions of the new § 150.31, an Agreement State must, after November 8, 1981, require compliance with standards for the protection of the public health, safety, and the environment from hazards associated with byproduct material which are equivalent, to the extent practicable, or more stringent than, standards in the new Appendix A of 10 CFR Part 40 discussed in Item 3 above. Before November 8, 1981, an Agreement State must require compliance with Appendix A of 10 CFR Part 40 to the maximum extent practicable. As discussed above, the provisions of the new Appendix A will require all mill operators to develop and submit detailed programs (which include appropriate supporting data, analyses, and alternatives) meeting the technical and financial criteria in the Appendix A in connection with license renewals or within nine months, whichever occurs first. The Commission believes that it is practicable for Agreement State licensees to develop and submit similar detailed programs to their respective licensing authorities in view of the length of time active milling operators have known of the basic components of these criteria and the nearly one year period before submittals are required. Therefore, the Commission expects Agreement States to immediately implement this requirement under the provisions of the UMTRCA which require Agreement States to implement equivalent standards "to the maximum extent practicable" during the interim period until November 8, 1981. The Commission notes in this regard that approval of a final acceptable plan (which may include various remedial alternatives for the management of existing tailings systems as well as alternatives for the management of tailings to be generated in the future) may take a long time following submittal of initial plans by licensees given the difficulty of the issues typically involved at existing sites. Thus, it is necessary for present mill operators to begin now to develop programs for meeting the standards in the new Appendix A to 10 CFR Part 40 rather than to delay until November 8, 1981, to develop plans and/or alternative programs for meeting the standards. Furthermore, the Commission considers it practicable now, even before final plans may have been worked out and approved, to immediately implement steps to reduce airborne effluent releases from both plant operations and tailings systems and seepage from tailings systems to levels which are as low as are reasonably achievable as specified in the standards of the new appendix. This is also required in order to meet the EPA standards in 40 CFR 190 which must be enforced by the Commission and Agreement States by December, 1980. Therefore, it is essential that licensing action be taken now to ensure interim tailings management programs which deal with presently occurring impacts such as blowing tailings and uncontrolled seepage are worked out on an immediate basis even before complete disposal programs can be finalized.

V. Future Actions

The UMTRCA establishes certain responsibilities and authorities whereby the Environmental Protection Agency (EPA) must develop standards of general application for the protection of the public health, safety, and the environment from radiological and nonradiological hazards associated with the processing and with the possession, transfer, and disposal of byproduct materials. These generally applicable standards for nonradiological hazards must provide for the protection of human health and the environment consistent with the standards required under subtitle C of the Solid Waste Disposal Act, as amended. The Commission and any State permitted to exercise authority under § 274b.(2) of the Atomic Energy Act must apply these standards of general application in licensing actions involving byproduct material.

The EPA has not, as yet, proposed the standards described above. It is the Commission's understanding, based on NRC and EPA staff discussions, that these standards will probably not be proposed before 1981. Upon finalization of the EPA standards, it is likely that minor changes will be required in the Commission's regulations. However, to delay issuance of the rules set forth below until the final EPA standards have been issued will, in all probability, preclude sufficient time for applicable Agreement States to adopt standards which are equivalent to or more stringent than those of the Commission's by November 8, 1981, in order to meet the requirements in the UMTRCA.

VI. Regulatory Changes

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, the Uranium Mill Tailings Radiation Control Act of 1978, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Code of Federal Regulations, Parts 30, 40, 70, and 150 are published as a document subject to codification.

46 FR 13971
Published 2/25/81
Effective 3/27/81

Disposal of High–Level Radioactive Wastes in Geologic Repositories: Licensing Procedures

See Part 60 Statements of Consideration

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46 FR 26471
Published 5/13/81
Effective 5/13/81 *

10 CFR Part 30

Amendment of Exemption for Ionizing Radiation Measuring Instruments

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its rules of general applicability to domestic licensing of byproduct material so that persons exempt from licensing and regulatory requirements may receive, use, and transfer ionizing radiation measuring instruments containing multiple internal calibration or standardization sources of byproduct material. The amendment is being adopted in response to a petition for rulemaking filed by General Atomic Company to permit distribution to exempt persons of multiple function instruments important to monitoring radiation and radioactive materials in and around major nuclear facilities. The action relieves all persons from the requirement to obtain a specific license to the extent that they receive, use, and transfer ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, sources of byproduct material each not exceeding the pertinent exempt quantity. An instrument may contain a total of 10 exempt quantities of byproduct material. The amendment should be of interest to manufacturers and users of ionizing radiation measuring instruments.

EFFECTIVE DATE: May 12, 1981.

FOR FURTHER INFORMATION CONTACT: Mr. D. A. Smith, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Telephone: 301/443-5946.

SUPPLEMENTARY INFORMATION: On February 25, 1981, the Nuclear Regulatory Commission published in the **Federal Register** (46 FR 14019) a notice of proposed amendments to 10 CFR Part 30 to permit the exempt use of multiple calibration sources in a radiation measuring instrument. Part 30 presently allows the exempt use of only a single calibration source in an instrument. The proposed change to permit use of multiple sources would enable users to obtain instruments with several internal sources so that calibration can be performed on a spectrum of radiation energies and more reliable measurements can be performed. Also, the proposed change would enable the use of multiple detectors with a single instrument and thus increase the number of samples measured in a given time period and reduce the cost per measurement.

The proposed amendments provided a period of 45 days for public comment. Two comments were received. Both comments were from manufacturers of radiation instruments and urged prompt adoption of final amendments. One of the manufacturers also suggested a minor change in the proposed amendments in order to allow greater flexibility in the design of instruments that may be used under the exemption. That suggestion concerned the number of radionuclides that could be contained in a single source or instrument. As indicated by the manufacturer, from the standpoint of health and safety the limitation of significance is the number of exempt quantities in a single source or a single instrument and the number of different radionuclides is not significant. The Commission agrees that the proposed amendments were unnecessarily restrictive with respect to the number of radionuclides that may be used in an instrument and the final rule does not limit an instrument to one exempt quantity of a particular radionuclide. Except for this change to allow greater flexibility in choice of radionuclides, the final amendment is substantially the same as the proposed amendments.

In the preamble to the final rule published in the **Federal Register** on April 22, 1970 (35 FR 6427), the Commission found that the exemption from licensing of ionizing radiation measuring instruments containing certain internal calibration or standardization sources under the conditions set forth in 10 CFR 30.15(a)(9) would not constitute an unreasonable risk to the common defense and security and to the health and safety of the public.

The Commission has found that the amendments set forth below are of a minor or nonpolicy nature, do not substantially modify existing regulations, and will not constitute an unreasonable risk to the common defense and security and to the health and safety of the public.

Regulatory Flexibility Certification

Since this amendment relieves persons from present regulatory restrictions, the Commission, in accordance with sec. 605(b) of the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), hereby certifies that this rule will not have a significant economic impact on a substantial number of small entities. Persons with a need for instruments with multiple internal calibration sources will be able to obtain those instruments without incurring the costs of a specific license.

Since the following amendment relieves rather than imposes restrictions under regulations currently in effect, it will become effective immediately upon publication pursuant to 5 U.S.C. 553(d).

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendment of Title 10, Chapter I, Code of Federal Regulations, Part 30, is published as a document subject to codification.

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46 FR 44418
Published 9/4/81
Effective 9/4/81

10 CFR Parts 30, 40, and 70

Regional Licensing Program

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The NRC is amending its regulations concerning the domestic licensing of byproduct material to provide information concerning the NRC's regional licensing program. The amendment specifies that applications or amendments for certain licenses must be sent to regional offices in regions where the regional licensing program is in effect. The amendment is necessary to inform current or prospective licensees of current NRC practice.

EFFECTIVE DATE: September 4, 1981.

FOR FURTHER INFORMATION CONTACT: Vandy L. Miller, NMSS, Telephone: (301) 427-4002.

SUPPLEMENTARY INFORMATION: The

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* 46 FR 27910

Nuclear Regulatory Commission is amending its regulations on communications concerning the domestic licensing of byproduct material to reflect current NRC practices under its regional licensing program. The revised communications provisions (§§ 30.6, 40.5, and 70.5) specify that all inquiries concerning NRC regulations in 10 CFR Parts 30–35, Part 40 and Part 70 and applications for certain types of licenses or license renewals or revisions in Regions I and III be sent to the regional office. This requirement would not apply to Agreement States, Federal facilities or the District of Columbia.

Background

The NRC conducted a two year pilot regional licensing program in Region III from March, 1978 to March, 1980. The program was designed to determine whether better service could be provided to licensees through field offices than would be given through Headquarters. The pilot program was also intended to determine the equipment and personnel needed for a formal regional program and to identify problems that could result from full regionalization.

Pilot Program Results

The pilot program indicated that better services to applicants and licensees can be provided by a regional licensing program. Under the pilot program, response time for licensing actions was reduced, the number of deficiency letters to applicants declined, and the quality of license reviews by the regional staff was consistent with that of the headquarters staff. In addition, the quality of license reviews and enforcement action as well as the training of licensing and inspection staffs benefited from the regional program.

As a result the NRC is continuing the regional licensing program in Region III and establishing a similar program in Region I.

The Regulation

The changes to §§ 30.6, 40.5, and 70.5 are nonsubstantive amendments. These amendments are intended to inform current and prospective licensees of current, NRC practices. The new §§ 30.6, 40.5, and 70.5 indicate the types of licenses covered under the regional licensing program and the proper addresses in Regions I and III for submitting covered licensing actions.

This is a nonsubstantive, administrative amendment. Since this is a minor procedural amendment the notice and comment procedures of the Administrative Procedure Act (5 U.S.C. 553) do not apply and good cause exists for making the amendment effective September 4, 1981.

Under the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended and 5 U.S.C. 552 and 553, the following amendments to 10 CFR Parts 30, 40, and 70 are published as a document subject to codification.

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46 FR 46875

Published 9/23/81

Effective 9/23/81

10 CFR Part 30

Exemption for Ionizing Radiation Measuring Instruments

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its rules of general applicability to domestic lincensing of byproduct material to add a small quantity of americium-241 to the list of radionuclides authorized for exempt use in ionizing radiation measuring instruments. The action relieves persons from the requirement to obtain a specific license or use an existing general license to the extent that they receive, use, or transfer ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, sources of byproduct material each not exceeding the exempt quantity of 0.05 microcurie of americium-241. The amendment should be of interest to manufacturers and users of ioninzing radiation measuring instruments.

EFFECTIVE DATE: September 23, 1981.

FOR FURTHER INFORMATION CONTACT: Mr. D. A. Smith, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Telephone: 301–443–5825.

SUPPLEMENTARY INFORMATION: On July 9, 1981, the Nuclear Regulatory Commission published in the Federal Register (46 FR 35523) a notice of proposed amendment to 10 CFR Part 30 to add a small quantity of americium-241 to the list of radionuclides authorized for exempt use as calibration sources in radiation measuring instruments. The sources are used for purposes of calibration or standardization and their use leads to more reliable radiation measurements.

The proposed amendment provided a period of 45 days for public comment. Three comments were received. Two comments were from users of radiation measuring instruments and the other comment was from an instrument manufacturer. All comments support the proposed rule. The instrument manufacturer also suggested that the proposed quantity limit of 0.005 microcurie of americium-241 in a single source be changed to 0.03 microcurie.

In response to the instrument manufacturer's comment about the quantity limit per source, the attached final rule provides for 0.05 microcurie of americium-241 per source. Selection of the 0.05 microcurie limit was based on the manufacturer's comment and on better information on industry practice than was considered in preparing the proposed amendment with its limit of 0.005 microcurie. For comparative purposes, it may be noted that NRC permits the exempt use of smoke detectors which typically contain 1 microcurie of americium-241 and that several million smoke detectors are distributed annually. It is unlikely that the distribution rate for radiation measuring instruments containing americium-241 sources will exceed a few hundred per year.

Except for the change in quantity limit of americium-241 per source from the proposed 0.005 to 0.05 microcurie, the final rule is the same as the proposed amendment. A suggestion by the instrument manufacturer that the provisions of § 30.15(a)(9) be revised to allow the exempt use of any calibration source used with an instrument and not only those sources contained in instruments, and a suggestion by a user that the proposed rule be revised to cover check sources, have not been adopted. Amendment of § 30.15(a)(9) to remove the long-standing restrictions that the source be contained in the radiation measuring instrument and used for internal calibration or standardization, would be outside the scope of the proposed rulemaking. Without considering the value of the suggestions, they have not been accommodated in the final rule because the public was not provided opportunity to comment on removal of these restrictions.

The Commission has found that the amendment set forth below is of a minor or nonpolicy nature, does not substantially modify existing regulations, and will not constitute an unreasonable risk to the common defense and security and to the health and safety of the public. The benefits of reduced administrative burden and reliable radiation measurements justify the very small, if any, potential environmental impact of this exemption. Because this amendment of 10 CFR 30.15(a)(9) is nonsubstantive and insignificant (from the standpoint of environmental impact), an environmental impact statement, negative declaration, or environmental impact appraisal need not be prepared in connection with this action.

Regulatory Flexibility Certification

Since this amendment relieves persons from present regulatory restrictions, the Commission, in accordance with sec. 605(b) of the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), hereby certifies that this rule will not have a significant economic impact on a substantial number of small entities. Persons with a need for instruments with americium-241 calibration sources will be able to obtain those instruments without incurring the costs associated with satisfying the requirements of a specific or general license.

Paperwork Reduction Act Statement

This final rule contains no new or amended requirements for recordkeeping, reporting, plans or procedures, applications, or any other type of information collection.

Since the following amendment relieves rather than imposes restrictions under regulations currently in effect, it will become effective immediately upon publication pursuant to 5 U.S.C. 553(d).

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendment of Title 10, Chapter I, Code of Federal Regulations, Part 30, is published as a document subject to codification.

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46 FR 55085
Published 11/6/81
Effective 11/6/81

10 CFR Parts 30 and 150

Removal of Certain Information Collection Requirements for Tritium

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations to remove two requirements for control and accounting procedures for tritium and two requirements for reporting transfers or receipts of tritium. The procedures and reports are no longer needed by the Commission to monitor inventory quantities of tritium at various locations in the U.S.

EFFECTIVE DATE: November 6, 1981.

FOR FURTHER INFORMATION CONTACT: James J. Henry, Office of Nuclear Regulatory Research, Nuclear Regulatory Commission, Washington, D.C. 20555, Telephone (301) 443-5981.

SUPPLEMENTARY INFORMATION: The Commission is removing from its regulations the following recordkeeping and reporting requirements:

(a) 10 CFR 30.54, Control and accounting procedures for tritium.

(b) 10 CFR 30.55(a), Tritium reports.

(c) 10 CFR 150.18, Control and accounting procedures for tritium.

(d) 10 CFR 150.19(a), Submission to Commission of tritium reports.

Since the beginning of fiscal year 1976, more than 99 percent of tritium shipped has been transferred by Government-owned, contractor-operated national laboratories. Although Commission regulations require reports of transfers or receipts of large quantities of tritium be submitted to the Department of Energy, the Commission does not monitor, utilize, or evaluate the reports. Finally, current information collection guidelines do not consider the collecting of data by one Federal agency for other Federal agencies to be sufficient reason for imposing an information collection requirement on the public.

Accordingly, the Commission has determined that the recordkeeping and reporting requirements set forth above are no longer needed to monitor inventory quantities of tritium at various locations in the U.S.

The Commission is also revising the center heading immediately preceding 10 CFR 30.51 to reflect the removal of the control and accounting procedures for tritium.

On November 30, 1980, the General Accounting Office's clearance of the information collection requirements in 10 CFR Part 30 expired. In the course of seeking a new expiration date for the clearance, the Commission informed GAO that it was not seeking clearance for 10 CFR 30.54 and 30.55(a) and would remove these requirements by means of rulemaking.

The Commission is now taking this rulemaking action along with removal of 10 CFR 150.18 and 150.19(a) which are conforming regulations containing recordkeeping and reporting requirements for Agreement State licensees authorized to possess, transfer, and receive large quantities of tritium.

Because the amendments set forth below relate to minor matters and are intended to provide relief from, rather than to impose, restrictions under regulations currently in effect, the Commission has found that good cause exists for omitting general notice of proposed rulemaking and public procedure thereon as unnecessary and for making the rule effective upon publication without the customary 30-day waiting period.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Parts 30 and 150 are published as a document subject to codification.

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47 FR 23138
Published 5/27/82
Effective 5/27/82

10 CFR Parts 30, 40, and 70

Regional Licensing Program

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The NRC is amending its regulations concerning the domestic licensing of source, byproduct, and special nuclear material to provide information concerning the further implementation of NRC's regional licensing program. The amendment specifies the categories of licensing actions for which full responsibility has been delegated to Regional Administrators. The amendment is necessary to inform current or prospective licensees of current NRC practice and organization.

EFFECTIVE DATE: May 27, 1982.

FOR FURTHER INFORMATION CONTACT: Vandy L. Miller, Office of Nuclear Material Safety and Safeguards, Telephone (301) 427-4002.

SUPPLEMENTARY INFORMATION: On September 7, 1981, the NRC amended its rules on licensing of certain nuclear materials so that licensees would communicate directly with Regions I and III (46 FR 44418). The Nuclear Regulatory Commission is again amending its regulation concerning the domestic licensing of source, byproduct and special nuclear material to reflect current NRC practices and assigned responsibilities under its regional licensing program. The revised provisions (§§ 30.6, 40.5, and 70.5) specify that inquiries concerning NRC regulations in 10 CFR Parts 30, 33, 35, 40 and 70 and applications for certain types of licenses or license renewals or revisions in Regions I and III be sent to the regional office. This requirement would not apply to Agreement States, Federal facilities or agencies of the District of Columbia.

The revised provisions do not change the requirements for direct communication between licensees and Regions I and III. With respect to the specific licensing actions delegated to the Regional Administrators, the revisions are intended to state more clearly exactly what licensing functions are now assigned to the Regional Administrators as their total responsibility under the Commission's regionalization program.

The basic delegation of authority for the Regional Administrators is contained in NRC Manual Chapter 0128. The general delegation requires supplementation, however, as specific functions are transferred to the Regional Offices. On May 13, 1982, the Executive Director for Operations and the Director of the Office of Nuclear Materials Safety and Safeguards executed a special delegation of authority to the Regional Administrators for Regions I and III. The functions fully and formally assigned to the regions are essentially those previously administered in the Regional offices under the regionalization pilot programs. The revised regulations reflect the pertinent provisions of the delegation of authority.

The changes to §§ 30.6, 40.5, and 70.5 are nonsubstantive amendments. The amendments are intended to inform current and prospective licensees of current NRC pratices and organization. The revised §§ 30.6, 40.5, and 70.5 indicate the type of licenses now fully delegated to Regional Administrators in Regions I and III and covered under the regional licensing program and the proper addresses in Regions I and III for submitting covered licensing actions.

Since this is a minor procedural amendment the notice and comment procedures of the Administrative Procedure Act (5 U.S.C. 553) do not apply and good cause exists for making the amendment effective May 27, 1982.

List of Subjects in 10 CFR Parts 30, 40, 70

Nuclear power plants, Nuclear materials.

Under the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended and U.S.C. 552 and 553, the following amendments to 10 CFR Parts 30, 40, and 70 are published as a document subject to codification.

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47 FR 27060
Published 6/23/82

10 CFR Parts 30, 40 and 70

Regional Licensing Program; Correction

In FR Doc. 82-14501 appearing at page 23138, in the issue of Thursday, May 27, 1982, make the following changes:

(1) On page 23139, middle column, in § 30.6, paragraph (b), introductory text, ninth line, the word "be" should follow after "Regions I and III must".

(2) On page 23140, in the first column, § 40.5, paragraph (b)(1), third line, a comma should appear after "modify" and before "suspend".

(3) On page 23140, middle column, in § 70.5, paragraph (b), introductory text, ninth line, "Regions I and II" should be changed to read "Regions I and III".

(4) On page 23140, third column, in § 70.5, paragraph (b)(2)(i), sixth line, the period that appears between "Delaware" and "Maine" should be a comma.

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47 FR 30452
Published 7/14/82
Effective 10/12/82

Protection or Employees Who Provide Information

See Part 19 Statements of Consideration

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47 FR 57446
Published 12/27/82
Effective dates:
10 CFR 20.311 of Part 20 effective date is 12/27/83; 10 CFR Part 61 and all other changes effective 1/26/83.

Licensing Requirements for Land Disposal of Radioactive Waste

See Part 61 Statements of Consideration

≫48 FR 16030
Published 4/14/83
Effective 4/1/83

10 CFR Parts 30, 40, and 70

Regional Licensing Program; Further Implementation

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The NRC is amending its regulations concerning the domestic licensing of source, byproduct, and special nuclear material (hereafter referred to as nuclear materials) to provide information about the expansion of NRC's decentralized licensing program. The amendment expands the program for materials licensees from Region I and III to include Regions II, IV, and V. Publication of the amendment is to inform present or prospective licensees of current NRC practice and organization.

EFFECTIVE DATE: April 1, 1983.

FOR FURTHER INFORMATION CONTACT: Vandy L. Miller, Chief, Material Licensing Branch.

ADDRESS: Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Telephone: (301) 427-4002.

SUPPLEMENTARY INFORMATION: On May 27, 1982, the Nuclear Regulatory Commission (NRC) amended its rules on the domestic licensing of nuclear materials to decentralize part of its licensing program (47 CFR 23138). The NRC is again amending its regulations concerning the domestic licensing of materials to expand decentralization of the licensing program. The revised provisions in §§ 30.6, 40.5, and 70.5 specify that inquiries concerning NRC regulations in 10 CFR Parts 30, 33, 35, 40, and 70, and applications for certain types of licenses, license renewals, and revisions be sent to the appropriate regional office, rather than NRC headquarters offices. These amendments do not apply to Agreement States and Federal facilities, but do apply to all other licensees and applicants in non-Agreement States and the District of Columbia. Delegations of authoriy to the Regional Administrators are contained in NRC Manual Chapter 0128. The changes to §§ 30.6, 40.5, and 70.5 are nonsubstantive amendments. The revised sections indicate the type of licensing authority delegated to Regional Administrators and the addresses for NRC regional offices. Since these are minor procedural amendments, the notice and comment procedures of the Administrative Procedure Act (5 U.S.C. 553) do not apply.

Paperwork Reduction Act Statement

This final rule contains no new requirement for recordkeeping, reporting, application, or any other type of information collection and, therefore, is not subject to the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501, et seq.).

List of Subjects in 10 CFR Parts 30, 40, and 70

Nuclear power plants, Nuclear materials.

Under the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552 and 553, the following amendments to 10 CFR Parts 30, 40, and 70 are published as a document subject to codification.

≫ 48 FR 32324
Published 7/15/83
Effective 8/15/83

10 CFR Parts 30, 40, and 70

Amendments Specifying Licensee Responsibility for Nuclear Materials and Procedures for Termination of Specific Licenses

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations to specify procedures for the termination of specific licenses authorizing possession and use of nuclear materials. The amendments clarify a licensee's authority and responsibility for nuclear materials and allow for orderly termination of specific licenses. The rule specifies that a license remains in effect, with respect to possession of residual nuclear materials present as contamination, until the Commission notifies the licensee, in writing, that the license is terminated. The rule is necessary to establish clear procedures for the termination of licenses and to establish a more coherent regulatory framework.

EFFECTIVE DATE: August 15, 1983.

FOR FURTHER INFORMATION CONTACT: K. G. Steyer, Chief, Chemical Engineering Branch, Office of Nuclear Regulatory Research, Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 443–5910.

SUPPLEMENTARY INFORMATION:

Background

On October 28, 1982, the Nuclear Regulatory Commission published in the **Federal Register** (47 FR 47400) a notice of proposed amendments to 10 CFR Parts 30, 40, and 70. The notice set forth procedures that a licensee would follow in terminating a specific nuclear materials license and clarified a licensee's responsibility for nuclear materials.

Discussion

Need for the rule. Previously, the Commission's regulations required licensees under 10 CFR Parts 30, 40, and 70 to notify the Commission, in writing, when the licensee decided to terminate operations. This requirement is continued in the final rule. Licensees were not required by regulation to describe the disposition of nuclear materials authorized under the license or to characterize radiological conditions at the time of license termination. The Commission has requested information concerning disposition of nuclear materials and decontamination on an individual-case-basis. Information concerning residual radioactive contamination has been requested only where it was suspected of being a problem. The rule is necessary to establish clear procedures for termination of licenses and to establish a more coherent regulatory framework. It will enable the Commission to determine that there is no significant risk to public health and safety before a licensee's responsibility for nuclear materials is terminated.

Requirements established by the rule. The rule requires each licensee, who does not apply for license renewal, to submit appropriate information concerning the disposal of licensed nuclear materials and on the absence or presence of residual radioactive contamination. If radiation levels are suitable for release, the Commission will notify the licensee, in writing, that the license is terminated.

If significant residual radioactive contamination is detected, the license continues in force, beyond the expiration date if necessary, with respect to possession of and responsibility for the residual radioactive contamination. The licensee must continue decontamination and control of contaminated areas until radiation levels are suitable for release and the Commission notifies the licensee, in writing, that the license is terminated. In addition, the licensee must submit a plan for decontamination and a final radiation survey report.

Analysis of Public Comments

The **Federal Register** notice provided a 60-day period for public comment. Letters containing a total of 21 comments were received from 12 commenters. Six letters were from electric power and utility companies (10 CFR Part 50 licensees), one from a nuclear fuel cycle licensee, three from consultant groups, and two from State and Federal agencies. Three comments specifically expressed support for the proposed rule and the remainder (18) suggested revisions, additions, and clarification. No comments specifically opposed the proposed rulemaking action. Copies of the comments may be examined in the Commission's Public Document Room at 1717 H Street NW., Washington, DC. The NRC response to the comments is presented below.

1. *Comment.* Many comments were directed at residual radioactivity levels. One commenter said that the rule requires a licensee to certify that no detectable radioactive contamination was found and that without specification of a lower level of detection the no detectable criteria standard is meaningless. Another commenter said that the word "detectable" should be replaced with the word "significant" [the commenter suggested that "significant" be defined as: Beta-gama exposure rates which are greater than twice background and/or soil concentrations of natural uranium greater than 40 picocuries per gram or radium-226 concentrations greater than 20 picocuries per gram]. Another commenter suggested that the rule changes should define the release criteria or "de minimis" radioactivity below which no further licensee control or decontamination is necessary, and referenced and NRC Inspection and Enforcement bulletin for criteria. Another commenter said that an upper level for nondetectable radioactive contamination needs to be established and that the statement "suitable for release for unrestricted use" needs clarification.

Response. Residual and "de minimis" radioactivity levels are outside the scope of this rule. The issue of residual radioactivity levels suitable for release for unrestricted use will be considered in a separate rulemaking action. Meanwhile, NRC will continue to provide guidance, on an individual-case-basis, on suitable levels of residual contamination for unrestricted release.

The rule requires that radiation survey reports be submitted unless the licensee can demonstrate the absence of residual radioactive contamination in some other manner. Further, the rule requires that survey instruments used in making radiation surveys be identified. Using these data the staff can determine a lower level of detection for the specific radionuclide involved and the validity of a radiation survey. There is no requirement to define lower level of detection in this rule. The reason for using the criterion of detectability is that a large number of small licensees (e.g., licensees with sealed sources and small possession limits) can demonstrate absence of residual radioactive contamination with minimal effort and expense.

2. *Comment.* A comment indicated that there should be standards for NRC's decision on whether a radiation survey report is required or not.

Response. The standard used by the staff in this determination is whether or not there may be significant amounts of residual radioactive contamination. In a large number of cases (e.g., where only sealed sources were used, or where short half-life and relatively small quantities of nuclear materials are possessed) a radiation survey report will not be necessary. Clarification is believed to be desirable and the rule is revised to indicate that submittal of a radiation survey report is not necessary if the licensee can demonstrate the absence of residual radioactive contamination without conducting a special radiation survey.

3. *Comment.* A comment stated that NRC should establish standards for determining when a decontamination plan is to be submitted.

Response. The *Regulatory Flexibility Act* section in the preamble of the proposed rule discussed this matter. It said that in some cases detectable residual contamination may be present, but the level may be suitable for release. In these cases, the licensee would not be required to submit a plan for decontamination. As indicated in the response to comment number 1, the NRC will provide guidance concerning suitable levels for release on an individual-case-basis.

4. *Comments.* Two comments were received concerning the statement in the preamble that read, "Prescribed fees for licensing services rendered by NRC would continue to be applicable until a license is terminated." One comment stated that NRC regulations do not contain prescribed fees for license termination services rendered by NRC. It said further that since NRC services rendered during termination of a license would not be comparable to services rendered during license renewal, it is not appropriate to charge the same fees. The comment suggested that NRC estimated, in the same manner used to derive the figures in 10 CFR Part 170, the time involved in terminating a license and establish a corresponding limit on the fees to be charged to a licensee for license termination. The other comment stated that the fees prescribed for licensing services associated with residual nuclear materials should be significantly less than those prescribed for the originally-licensed facility.

Response. It is present Commission policy not to charge fees for Parts 30, 40, and 70 applications requesting termination of licenses. The language questioned by these comments was intended to mean that if any routine inspection was conducted before or after the expiration date of the license but before the license was terminated, the Commission would assess a fee for the inspection since the license was valid at the time the inspection was conducted. Under the current fee schedule, any nonroutine (close-out) inspection is not charged to the licensee.

5. *Comment.* One comment stated that the word "immediately" [in §§ 30.36(b), 40.42(b), and 70.38(b) in regard to written notification when a licensee decides to terminate operations] should be clarified or defined. This comment suggested that licensees should notify the Commission 90 days prior to vacating the premises.

Response. A licensee may decontaminate and terminate projects at any time under an active license. However, license termination procedures can be most expeditiously followed if a licensee notifies the Commission as soon as the licensee decides to terminate operations. The intent of the rule is that decontamination should be accomplished and the license terminated as soon as practical, after the licensee decides to terminate operations.

6. *Comment.* One comment suggested that licensees should be allowed to continue some or all normal activities while decontamination activities are conducted.

Response. Normal operating activities can be continued during decontamination as long as the license has not expired. But, unless the licensee makes timely application for license renewal, nuclear materials must be transferred or disposed of before the license expiration date. Only activities related to decontamination and control of nuclear materials are permitted beyond the license expiration date, unless a timely license renewal application has been submitted (i.e., 30 days or more before the license expiration date).

7. *Comment.* A concern of several public utility companies (10 CFR Part 50 licensees) is how the new rule affects them in relation to licenses issued to possess and use nuclear materials under 10 CFR Parts 30, 40, and 70.

Response. Production and utilization facility licensees (10 CFR Part 50 licensees) may be issued licenses to possess and use byproduct, source, and/or special nuclear material, before they receive an Operating License for the facility. If the license to possess and use nuclear materials expires before an Operating License is issued, it must be renewed or terminated. Renewal is usually accomplished by amending the nuclear materials license to extend the expiration date, which is done by license condition. If the holder of a Construction Permit decides to terminate a nuclear materials license, e.g., a new fuel license issued under Part 70, before a Part 50 Operating License is issued, the requirements of this rule apply. When a Part 50 Operating license is issued, the nuclear materials license is automatically terminated. Requirements for posssession and use of nuclear materials are contained in the Part 50 Operating License and the requirements of this rule do not apply. No revision to the rule is necessary to accommodate these comments.

8. *Comment.* One comment stated that the substance of Form 314 was not made part of the rule nor the explanation of the proposed rule. The comment suggested it be made part the final rule.

Response. NRC Form 314, "Certification of Disposition of Materials," is sent to each NRC materials licensee 90 days before expiration of the license. This form requests information as to whether or not nuclear materials have been procured. It also requests information concerning disposal of nuclear materials, such as transfer to an NRC licensee, transfer to an Agreement State licensee, or disposal in some other manner. NRC Form–314 is used to obtain information concerning termination of specific licenses. OMB recently approved this form under approval number 3150–0028. As part of the approval process it was determined that this form, and the information required by it, is the best method of obtaining this information. Because the information required by the form is not a subject of this rulemaking action, it is not necessary to include the contents of the form in the rule.

9. *Comment.* One comment stated that there was no mention in the proposed rule as to the effective date of the amendments and whether licensees who have submitted requests for decommissioning or license termination prior to the passage of the rule are exempt.

Response. These amendments will codify procedures that are currently being used on an individual-case-basis. This rule does not significantly alter existing procedures. It is intended that the rule changes be made effective in the usual manner, that is 30 days following notice of final rulemaking published in the **Federal Register.** The provisions of the rule are applicable to any licensee who decides to terminate a license after this date.

Changes from proposed rule. There have been no significant revisions to the proposed rule as a result of public comments or reviews during final rulemaking procedures. However, several changes of a clarifying or editorial nature have been made. The changes are as follows:

1. Editorial changes have been made in §§ 30.36(b) and (e), 40.42(b) and (e), and 70.38(b) and (e).

2. It was apparently not clear in the proposed rule that licensees may decontaminate affected facilities prior to the license expiration date. Changes have been made in §§ 30.36(d)(1) and (3), 40.42(d)(1) and (3), and 70.38(d)(1) and (3) to clarify that licensees are authorized to conduct decontamination activities, in fact must decontaminate to the extent practicable, before the license expires.

3. Changes have been made in §§ 30.36(d)(1)(v)(A) and (B), 40.42(d)(1)(v)(A) and (B), and 70.38(d)(1)(v)(A) and (B) to (1) clarify that submittal of a radiation survey report is not necessary if a licensee can demonstrate absence radioactive contamination without conducting a survey, (2) add units for reporting radioactive contamination in water and indicate that not all of the units listed are appropriate for all licensees, and (3) specify that instruments used in radiation surveys must be working properly.

Environmental Impact

These amendments clarify requirements for termination of a licensee's responsibility for nuclear materials. The amendments do not add substantive requirements from an environmental viewpoint. Environmentally they are nonsubstantive and insignificant. No environmental impact statement, appraisal, or negative declaration needs to be prepared under 10 CFR 51.5(d)(3).

Paperwork Reduction Act Statement

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3510, et. seq.). These requirements were approved by the Office of Management and Budget under approval numbers: Part 30–3150–0017; Part 40–3150–0020; and Part 70–3150–0009.

Regulatory Analysis

The NRC has prepared a regulatory analysis on this regulation. The analysis examines the benefits and costs of the alternatives considered by the staff. Interested parties may examine a copy of the regulatory analysis at the Commission's Public Document Room at 1717 H Street NW., Washington, DC. Single copies of the analysis may be obtained from W. R. Pearson, Chemical Engineering Branch, Office of Nuclear Regulatory Research, Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 443–5910.

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980, the Executive Director for Operations certifies that this action will not have a significant economic impact on a substantial number of small entities.

The rule applies to the Commission's approximately 8,100 materials licensees under 10 CFR Parts 30–35, 40, and 70. These licensees include about 5,000 byproduct material licenses under Parts 30, 32, 33, and 34, 2,000 medical licenses under Part 35, 400 source material licenses under Part 40, and 700 special nuclear material licenses under Part 70. The rule affects about 200 NRC licensees per year who wish to terminate operations.

The NRC estimates that about 90% of the affected licensees would be considered small entities under the criteria set out in the size standards of the Small Business Administration in 13 CFR Part 121 (e.g., most licensees with less than 500 employees, hospitals with less than 150 beds, other medical licenses with less than $1.5 million annual gross receipts). In developing the rule, the NRC specifically considered the potential problems that would face a small entity under these requirements. The NRC has attempted to structure the requirements to mitigate the economic effect of the rule on small entities to the extent possible considering the Commission's responsibility for public health and safety. Although there is not an absolute correlation between the size of a licensee and the requirements of the regulation, in general, the regulation will have minimal incremental impact on most small licensees.

This rule specifies the procedures to be followed when a licensee desires to terminate a materials license. Each licensee is required to—

1. Submit a form NRC–314 that describes the disposal of licensed materials;

2. Submit a final radiation survey, unless the licensee demonstrates the absence of residual radioactive contamination in some other manner; and either:

3. Submit a certification that residual radioactive contamination attributable to activities conducted under the license is not detectable; or

4. Where residual radioactive contamination is present, submit a radiation survey report and a plan for decontamination, if required. In some cases, detectable residual contamination may be present, but the level may be suitable for release. In these cases, the licensee will not be required to submit a plan for decontamination.

The NRC believes that about 99% of the small entities affected by the rule will be able to comply with the requirements by following the simplest procedure. These licensees would submit a form NRC–314 and certify that no residual contamination attributable to activities conducted under the license is present. Data collection for form NRC–314 is similar to actions performed during regular operations. Some clerical and management time is required to complete the form and submit it. The average impact on small licensees, as a result of requiring submittal of a form NRC–314, is estimated to be less than an hour at an approximate cost of $20. Submittal of a certification letter would require only clerical and management personnel. Preparation and submittal of this letter would probably require about an hour at an approximate cost of $20. NRC Form–314, as approved by OMB, has been revised to contain provisions for certification, which will reduce this cost. It is estimated that the total impact on small licensees under the simple procedure will be about one-half person-day of effort at an approximate cost of $80. Some licensees will also be required to submit a final radiation survey report. However, many licensees will not, in particular licensees with sealed sources and byproduct licensees with small license possession limits and short half-life materials. A radiation survey must be conducted by qualified personnel (usually a health physics technician), the report assembled, and submitted. In cases involving extensive contaminated areas some land surveying, sample drilling, and special analyses may be involved. These actions involve health physics, management, clerical, and possibly other types of personnel. On the average for small licensees the impact of submitting radiation survey reports is estimated to be less than one-half person-day at a cost of approximately $80. For some larger licensees the average is estimated to be about two person-days at a cost of approximately $320.

The NRC believes that less than 1% of the affected small licensees will be required to submit a decontamination plan. This action will require the average small licensee to expend about one-half person-day of effort at an approximate cost of $80. A comparable effort might require the average larger licensee to expend about four person-days of effort at approximate cost of $840. Preparation and submittal of a decontamination plan requires use of technical, management, clerical, and possibly other types of personnel. Preparation of this plan would be facilitated by using technical and management personnel familiar with the operations.

List of Subjects

10 CFR Part 30

Byproduct material, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Penalty, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 40

Government contracts, Hazardous materials—transportation, Nuclear materials, Penalty, Reporting and recordkeeping requirements, Source material, Uranium.

10 CFR Part 70

Hazardous materials—transportation, Nuclear materials, Packaging and containers, Penalty, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Security measures, Special nuclear material.

Final Rulemaking

The NRC is adopting the following amendments to 10 CFR Parts 30, 40, and 70 under the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553.

➤ 48 FR 39036
Published 8/29/83
Effective 9/28/83

10 CFR Parts 30, 70 and 150

Irretrievable Well-Logging Sources

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations to establish requirements to be accomplished in the event of an irretrievable well-logging source (any sealed source containing licensed material that is pulled off or not connected to the wireline that suspends the source in the well for which all reasonable effort at recovery has been expended). The final rule establishes requirements for sealing and protecting the well-logging source, identifying the well site, and reporting the occurrence. The Commission believes that uniform and adequate safety requirements contained in this rule are necessary to ensure that no subsequent damage to the source occurs that might result in the dispersal of radioactive material.

EFFECTIVE DATE: September 28, 1983.

ADDRESSES: Copies of the Regulatory Analysis and analysis of comments may be examined at the Commission's Public Document Room at 1717 H Street NW., Washington, DC 20555.

FOR FURTHER INFORMATION CONTACT: Dr. Anthony N. Tse, Office of Nuclear Regulatory Research, Washington, DC 20555, telephone (301) 443–7902.

SUPPLEMENTARY INFORMATION: A well-logging operation consists of lowering into and raising from wells on a wireline a well-logging tool, a measuring device, which may contain sealed radioactive sources. The purpose of the well-logging operation is to obtain information about the underground strata. Currently, the Commission has approximately 160–170 licensees authorized to conduct well-logging activities and over 50,000 wells are logged each year. Sealed radioactive sources used in well-logging operations typically contain americium–241 or cesium–137 sources.

Occasionally a well-logging tool containing a radioactive source becomes disconnected from the wireline. In some instances, the well-logging tool is unrecoverable and is left in the well. An irretrievable well-logging source is any sealed source containing licensed material that is pulled off or not connected to the wireline that suspends the source in the well and for which all reasonable effort at recovery has been expended. A review of records indicates that an average of five irretrievable well-logging sources has occurred yearly.

A well containing an irretrievable well-logging source could continue in production. Operation such as redrilling could be performed in that well. If an irretrievable well-logging source was damaged by subsequent operation and radioactive material was brought to the surface, contamination of the well-site, drilling equipment, vehicles, and personnel could occur.

Currently, the Commission treats the abandonment of an irretrievable well-logging source as a condition of the well-logger's license. The licensee is required to specify the procedures that will be used in the abandonment and identification of an irretrievable well-logging source. Because some logging companies operate on an interstate basis and because these activities are licensed by the Commission and the Agreement States, uniformity in the content and application of abandonment procedures is important. In addition, legally binding requirements are required to assure that the well owner or operator performs the required actions when neither the owner or operator is the licensee. This regulation is intended to provide the uniformity and assurance necessary to assure radiological safety in the event of an irretrievable well-logging source.

On September 28, 1978 the NRC published in the **Federal Register** (43 FR 44547) a notice of proposed rulemaking setting out amendments to 10 CFR Parts 30 and 70 that would require certain procedures be followed if a well-logging tool containing radioactive material was abandoned in a well. These procedures include sealing the source in place with a cement plug, mounting a permanent identification plaque at the surface of the well and reporting the circumstances concerning the irretrievable source to the Commission and to pertinent State agencies within 30 days after the source had been abandoned. The notice provided for a 60-day public comment period.

Ten letters of comment were received in response to the notice. All 10 commenters expressed general agreement with the purpose of the proposed regulations. However, most commenters did express concern about some aspect of the proposed amendments.

Six commenters observed that the definition of an irretrievable well-logging source required the Commission to determine when all reasonable effort at recovery had been expended. These commenters complained that the Commission had neither the expertise nor the resources to make this determination. Although it was never intended that the Commission unilaterally decide whether a source was irretrievable, the definition has been amended to delete the reference to unilateral Commission determination of the status of the source. Accordingly, the phrase "as determind by the Commission" has been deleted from the definition. However, under §§ 30.56(b) and 70.60(b) as revised, the Commission retains the authority to determine if "all reasonable effort at recovery has been expended" and may deny approval of the abandonment procedures if it feels that this condition has not been met.

Six commenters noted a discrepancy between the language of the proposed amendment and the intent of the amendment regarding a written agreement between the licensee and the well owner or operator. This agreement would require execution of the abandonment procedures when required and within a specific time period. These commenters correctly noted that the language did not reflect the intent of the regulations. Accordingly, the regulations in 10 CFR 30.56(a) and 70.60(a) have been revised to clarify that a written agreement between the licensee and the well owner or operator is required prior to commencement of well-logging activities and that agreement must assure implementation of proper abandonment procedures within thirty days after a well-logging source is declared irretrievable.

One commenter further stated that an executed agreement may be difficult to enforce since neither the well owner nor the well operator is a Commission licensee. The Commission considers the well-logger, as a licensee, responsible for ensuring compliance with the regulations or for pursuing every legal avenue to achieve that compliance. In view of this licensee responsibility, the changes in the regulations proposed by this commenter are not adopted.

Five commenters noted that too much wording was required on the identification plaque. In particular, these commenters stated that much of the information would be available in the report filed with the State and Commission or that some information, such as the name and address of the well owner or operator may be incorrect by the time a well is reentered. These comments were accepted in part. The amendment as revised requires that the plaque contain only information that the Commission considers essential to warn persons of the potential hazard that may be encountered when the well is reentered.

Three commenters suggested that the licensee have the option of reporting the incident to either the Commission or to the appropriate State regulatory authority. The Commission disagrees. All Commission licensees are required to notify the Commission of incidents involving radioactive materials. The Commission also believes that notification of the appropriate State regulatory agency is an important safety requirement since a warning notation is needed in the well records. In addition, the amendments in 10 CFR 30.56 and 70.60 specifically state the information that the report must contain. In view of these considerations, notifications are required for both the Commission and the State regulatory agency.

After careful consideration of the comments on the notice of proposed rulemaking, the Commission has adopted the amendments in final form. The requirements of §§ 30.56(a) and 70.60(a) relating to agreements between the well-logger (licensee) and the well owner or operator will not apply to job sites where operations have begun prior to the effective date of these amendments. The requirements of §§ 30.56(b), 30.56(c), 30.56(d), 70.60(b), 70.60(c), and 70.60(d) will apply to all well-logging sources abandoned after the effective date of these amendments.

In addition to the amendments to 10 CFR Parts 30 and 70, the Commission is also amending 10 CFR Part 150 without public comment. Section 150.20 currently references § 30.56, but not § 70.60. The amendment will correct this difference. Because the amendment to § 150.20 is nonsubstantive and conforming in nature, the Commission has found that good cause exists for omitting notice of proposed rulemaking, and public procedure thereon, as unnecessary and for making the effective date of this amendment coincide with the effective date of the amendments to §§ 30.56 and 70.60.

Paperwork Reduction Act Statement

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3510, et seq.). These requirements were approved by the Office of Management and Budget under approval numbers: Part 30—3150–0017; and Part 70—3150–0009.

Regulatory Analysis

The Commission has prepared a regulatory analysis for this regulation. The regulatory analysis examines the costs and benefits of the alternatives considered by the Commission. Interested persons may examine a copy of the regulatory analysis at the Public Document Room, 1717 H Street NW., Washington, DC. Single copies of the analysis may be obtained from Dr. Anthony N. Tse, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone: (301)443–7902.

List of Subjects

10 CFR Part 30

Byproduct material, Government contracts, intergovernmental relations, Isotopes, Nuclear materials, Penalty, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 70

Hazardous materials-transportation, Nuclear materials, Packaging and containers, Penalty, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Security measures, Special nuclear material.

10 CFR Part 150

Hazardous materials-transportation, Intergovernmental relations, Nuclear materials, Penalty, Reporting and recordkeeping requirements, Security measures, Source material, Special nuclear material.

Under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the following amendments to 10 CFR Parts 30 and 70, and 150 are published as a document subject to codification.

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49 FR 9352
Published 3/12/84
Effective: Upon approval of OMB or 6/7/84.

Environmental Protection Regulations for Domestic Lincensing and Related Regulatory Functions and Related Conforming Amendments

See Part 51 Statements of Consideration

≫ **49 FR 19623**
Published 5/9/84
Effective 5/9/84

Information Collection Requirements; Display of OMB Control Numbers

See Part 0 Statements of Consideration

≫ **49 FR 19630**
Published 5/9/84
Effective 4/2/84

10 CFR Parts 30, 40 and 70

Regional Licensing Program; Further Implementation

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The NRC is amending its regulations concerning the domestic licensing of source, byproduct, and special nuclear material (hereafter referred to as nuclear materials) to provide information about the additional implementation of NRC's decentralized licensing program. This amendment broadens the scope of the program in all Regions to include additional types of nuclear material licenses. Publication of the amendment is to inform present or prospective licensees of current NRC practice and organization.

EFFECTIVE DATE: April 2, 1984.

FOR FURTHER INFORMATION CONTACT: Donald R. Chapell, Deputy Director, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Telephone: (301) 427–4152.

SUPPLEMENTARY INFORMATION: On May 27, 1982 (47 FR 23136) and again on April 14, 1983 (48 FR 16030) (effective April 1, 1983), the Nuclear Regulatory Commission (NRC) published rules amending the domestic licensing of nuclear materials to decentralize parts of its licensing program. The NRC is again amending its regulations to broaden further the scope of its decentralization program. These revisions to §§ 30.6, 30.32, 40.5, 40.31, 70.5, and 70.21 specify that inquiries concerning NRC regulations in 10 CFR Parts 30 through 35, 40, and 70 and applications for additional types of licenses, license renewals, and revisions be sent to the appropriate regional office, rather than NRC headquarters offices. Included in this action are licenses in the following categories: teletherapy, well-logging, industrial radiography, irradiatorr, nuclear pharmacies, medical product distribution, measuring systems, nuclear laundries, receipt of radioactive waste, generally licensed distributions, pacemakers and other smaller categories of nuclear material licenses.

This action transfers the responsibility to license the distribution of radioactive material to specific and general licensees to the Regional Offices. Regional Offices also become responsible for licensing actions concerning the manufacture of products containing radioactive material to persons exempt pursuant to 10 CFR 32.11 through 32.26. However, the responsibility for the licensing of the distribution of products containing radioactive material to persons exempt prusuant to 10 CFR 32.11 through 32.26 remains at NRC Headquarters. These amendments do not apply in Agreement States or to Federal facilities, but do apply to all other licensees and applicants in non-Agreement States, Guam, Puerto Rico, the Virgin Islands, and the District of Columbia.

Delegations of authority to the Regional Administrators are contained in NRC Manual Chapter 0128. The changes to §§ 30.6, 30.32, 40.5, 40.31, 70.5 and 70.21 are nonsubstantive amendments. The revised sections indicate the type of licensing authority delegated to Regional Administrators.

Other changes have been made to delete Utah from the list of Non-Agreement States in Region IV. Utah became an Agreement State on April 1, 1984.

Since these are minor, procedural amendments relating to agency organizational and management; notice, opportunity for comment and a delay of effective date are not required by the Administrative Procedure Act. (5 U.S.C. 553).

Paperwork Reduction Act Statement

This final rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). Existing requirements were approved by the Office of Management and Budget approval numbers 3150–0017 for Part 30, 3150–0020 for Part 40, and 3150–0009 for Part 70.

List of Subjects

10 CFR Part 30

Byproduct material, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Penalty, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 40

Government contracts, Hazardous materials-transportation, Nuclear materials, Penalty, Reporting and recordkeeping requirements, Source material, Uranium.

10 CFR Part 70

Hazardous matrials-transportation, Nuclear materials, Packaging and containers, Penalty, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Security measures, Special nuclear material.

Under the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552, the following amendments to 10 CFR Parts 30, 40, and 70 are published as a document subject to codification.

49 FR 21699
Published 5/23/84
Effective 5/23/84

Information Collection Requirements, Display of OMB Control Numbers

See Part 0 Statements of Consideration

49 FR 24512
Published 6/14/84
Effective 6/7/84

Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions and Related Conforming Amendments

See Part 2 Statements of Consideration

49 FR 24705
Published 6/15/84
Effective 7/16/84

10 CFR Parts 30, 40, and 150

Tritium and Source Material Reports

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its requirements applicable to NRC and Agreement State licensees who transfer or receive other than U.S. origin source material, or who import or export source material of any origin. For those licensees, the reportable quantity of certain source material transfers is lowered from 1,000 kilograms to 1 kilogram. This action is necessary to satisfy existing international commitments. Reporting requirements for all other transfers of source material, except for facilities selected by the IAEA, have been deleted. The NRC is also removing the requirement that all NRC and Agreement State licensees report tritium inventories. The NRC determined that tritium inventory reports are not necessary for conduct of its regulatory programs.

EFFECTIVE DATE: July 16, 1984.

FOR FURTHER INFORMATION CONTACT: June Robertson, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone: (301) 427–4004.

SUPPLEMENTARY INFORMATION:

Background

The NRC Safeguards staff conducted a study to reexamine several assumptions underlying the proposed development of an Integrated Safeguards Information System. One of the issues examined was the need for the current safeguards reporting requirements placed on licensees. The staff concluded that all material transfer and inventory data that licensees are currently required to report to NRC are necessary to satisfy existing international commitments and domestic safeguards needs, with the

exception of the requirement to report tritium inventories. Subsequent to the study, further examination indicated that requirements applicable to source material transfer reports should be changed to reflect existing international commitments. On November 29, 1983, the Commission published proposed amendments in the **Federal Register** (48 FR 53714) to eliminate the tritium reporting requirements and change the source material transfer report requirements as suggested by the examination.

The proposed amendments also suggested changes for clarity that included deleting specific addresses from the regulation and stating that requirements of these parts are not applicable to general licensees. A sixty-day comment period expired on January 30, 1984. Comments were received from nineteen respondents.

Summary of Public Comment

The proposed amendments have been modified in response to the comments received and will be published in final form, as modified, to become effective 30 days after publication of this notice. The changes which were made in response to public comments were primarily for the purpose of clarification and are consistent with the intent of the Commission at the time of publication of the proposed amendments. A summary of the public comments and, where appropriate, a description of the changes that resulted from them follows:

1. *Need for these amendments.* All but three of the commenters questioned the need for lowering the reportable quantity of non-nuclear end use source material transfers. These commenters included small licensees who utilize source material in their operations for testing, research, development, education, manufacturing, and repackaging and the Department of Defense organizations who utilize source materials in munitions. These commenters suggested that all non-nuclear end use materials that are not needed to satisfy existing international commitments be exempt from the transfer reporting requirements. Three of these commenters suggested that source material used in the manufacture of non-nuclear end use devices be exempt from the transfer reporting requirement at the time the material enters the manufacturing process.

The NRC has determined that transfers involving source material that has been incorporated in non-nuclear end use products do not have to be reported to satisfy existing international commitments. The licensees' suggestions have been adopted by the rewording of §§ 40.64(d)(4) and 150.17(d)(4), which provide for the exemption of reports for those transfers which involve material contained in non-nuclear end use **devices or components. Also, §§ 40.64(a) and 150.17(a) have been reworded to specify that reports are required only for those transfers that involve material of international concern. These changes will reduce the reporting burden.**

With respect to the proposed amendment, comments received not resulting in changes follow:

1. Two of the commenters expressed concern about the deletion of the requirement to report inventories of tritium. They felt that in the absence of a report of tritium inventory, the NRC could not regulate disposal of tritium and therefore tritium could be easily dispersed into the environment.

With the deletion of the tritium reporting requirements, licensees will continue be subject to license conditions and other safety requirements. Also, the requirement to dispose of tritium and to keep records of disposal will remain. The NRC will delete the requirement to report inventories of tritium because the reporting of holdings of tritium is not necessary for the conduct of the NRC safety and safeguards regulatory programs.

2. One commenter was concerned that general license holders who are authorized under § 40.22 to use and transfer up to 15 pounds (approximately 7 kilograms) of source material would now be required to report transfers of 1 kilogram or more.

One of the published amendments made for clarity to § 40.64 indicates that the requirement to report transfers is not applicable to general license holders.

3. Two commenters questioned the need for reports of source material transfers at the 1 kilogram level to satisfy international commitments. They indicated that 1 kilogram of source material has little strategic significance. Reference was made to "1 effective kilogram" of source material in 10 CFR Part 75 which was promulgated to implement the US/IAEA Safeguards Agreement.

The reference to "1 effective kilogram" in 10 CFR Part 75 applies to advance notification of proposed imports and exports and domestic transfers when shipped to a facility that is not eligible for the application of IAEA safeguards. The international commitments require reports on all transfers of nuclear materials. However, as a matter of convenience, the IAEA participants charged with implementing the international agreements agreed upon one kilogram as the quantity to be used for reporting purposes.

Environmental Impact: Categorical Exclusion

The NRC has determined that the amendments to 10 CFR Parts 30 and 40 in this final regulation are the type of action described in categorical exclusion 10 CFR 51.22(c)(3). The NRC has determined that the amendment to 10 CFR Part 150 in this final regulation is the type of action described in 10 CFR 51.22(c)(1). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this proposed regulation.

Paperwork Reduction Act Statement

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). This rule had been approved by the Office of Management and Budget, OMB Approval Nos. 3150–0003, 3150–0017, 3150–0020, and 3150–0032.

Regulatory Analysis

The NRC has prepared a regulatory analysis on this final regulation. The analysis examines the costs and benefits of the alternatives considered by the NRC. The analysis is available for inspection in the NRC Public Document Room, 1717 H Street NW, Washington, DC. Single copies of the analysis may be obtained from June Robertson, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone: (301) 427–4004.

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission hereby certifies that this rule does not have a significant economic impact upon a substantial number of small entities due to the small number of reports involved. The rule affects about 60 specific source material licensees. Approximately 10 of these licensees are large industrial manufacturers who submit approximately 60 reports each per year that are not required by the current rule. The remaining 50 affected licensees are small independent industrial manufacturers with an average annual gross income of less than $1 million and employ fewer than 500 people who are not presently reporting at the one kilogram level. The small industrial licensee will submit an average of two reports per year.

The total time required by a licensee to complete each transfer report is estimated at approximately 1 hour. This is time needed to complete the report. No research or compilation is necessary **as all information is transcribed from bills of lading, in-house records kept for other purposes, sales agreements, etc. The annual burden is about 2 hours per small industrial licensee and approximately 60 hours per large industrial licensee to perform the proposed reporting for a total combined annual burden of approximately 700** hours.

The costs for complying with the source material reporting requirement will not pose a significant economic impact. The additional cost for each of the small licensees will be approximately $120. The annual cost for each large licensee will be approximately $3,600. The total additional burden for all affected licensees will be approximately $42,000. This cost impact is lessened by the fact that some licensees are already reporting voluntarily. Furthermore, approximately 5,000 reports of no international interest will be eliminated for a $300,000 annual reporting burden reduction.

Calendar year 1981 was the most recent year that an inventory of tritium was reported. During that year, one licensee submitted one tritium inventory report. An estimated 1 hour is required to complete one inventory report. Consequently, it is estimated that the present reporting burden would be reduced by 1 hour per year.

List of Subjects

10 CFR Part 30

Byproduct material, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Penalty, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 40

Government contracts, Hazardous materials—transportation, Nuclear materials, Penalty, Reporting and recordkeeping requirements, Source material, Uranium.

10 CFR Part 150

Hazardous materials—transportation, Intergovernmental relations, Nuclear materials, Penalty, Reporting and recordkeeping requirements, Security measures, Source material, Special nuclear material.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is adopting the following amendments to 10 CFR Parts 30, 40, and 150.

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49 FR 27923
Published 7/9/84
Effective 7/9/84

10 CFR Parts 30, 33, 34, 35, and 40

Application Consolidation to NRC Form 313; Application for Material License

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The NRC is amending its regulations concerning the domestic licensing of source and byproduct material to provide for consolidation of five application forms into one simplified form for applications for material licenses. The consolidation simplifies the regional review process and provides an improved format for automatic data entry of information submitted.

EFFECTIVE DATE: July 9, 1984.

FOR FURTHER INFORMATION CONTACT: Bernard Singer, Chief, Material Certification and Procedures Branch, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: 301-427-4236.

SUPPLEMENTARY INFORMATION: On May 27, 1982 (47 CFR 23136), the Nuclear Regulatory Commission (NRC) amended its rules on the domestic licensing of nuclear materials to begin decentralization of its licensing program to the Regional Offices. As a part of this program, currently used NRC Forms 2 and 313 I, M, R, and T are being combined into a new NRC Form 313, "Application for Material License." This standardization of forms will foster the uniformity of the review process. Additionally, the applicant will not have to determine which of five forms is the correct one to use for its application.

There is no change in the information collection required for the submission of an application or issuance of an NRC license. There are, however, four added voluntary questions at the end of the form that request certain economic data. This change is for the convenience of the NRC. The new format will simplify the work of the reviewers by having information of the same type, i.e., "Radiation Protection" appear in the same location for all types of applications thereby saving the reviewer orientation time in reviewing different types of license applications. The continuing move toward automatic data entry of information from license applications dictated that a uniform format be developed to assist in this important function. The revised provisions in §§ 30.32, 33.12, 34.3, 35.4 and 40.31 specify that applications for use of byproduct and source material may be submitted in duplicate on NRC Form 313, "Application for Material License." These amendments do not apply to Agreement States, but do apply to all licensees and applicants in non-Agreement States and the District of Columbia.

Because this is an amendment dealing with agency practice and procedure, the notice provisions of the Administrative Procedure Act do not apply pursuant to 5 U.S.C. 553(b)(A). The amendment is effective upon publication in the Federal Register, because good cause exists to dispense the usual 30 day delay in the effective date. The amendment is of a minor and technical administrative nature dealing solely with agency procedure. The rule simplifies the license application process and establishes uniformity in the NRC license review.

Paperwork Reduction Act Statement

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget under control number 3150-0120.

List of Subjects

10 CFR Part 30

Byproduct material, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Penalty, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 33

Byproduct material, Nuclear materials, Penalty, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 34

Packaging and containers, Penalty, Radiation protection, Radiography, Reporting and recordkeeping requirements, Scientific equipment, Security measures.

10 CFR Part 35

Byproduct material, Drugs, Health facilities, Health professions, Incorporation by reference, Medical devices, Nuclear materials, Occupational safety and health, Penalty, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 40

Government contracts, Hazardous materials—transportation, Nuclear materials, Penalty, Reporting and recordkeeping requirements, Source material, Uranium.

Under the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552, the following amendments to 10 CFR Parts 30, 33, 34, 35 and 40 are published as a document subject to codification.

≫ **49 FR 47823**
Published 12/7/84
Effective 12/7/84

Minor Correcting Amendments

See Part 1 Statements of Consideration

50 FR 14692
Published 4/15/85
Effective 4/1/85

10 CFR Parts 30, 40 and 70

Regional Nuclear Materials Licensing for Certain Federal Facilities

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The NRC is amending its regulations concerning the domestic licensing of source, byproduct, and special nuclear material (collectively referred to as nuclear materials) to provide for further decentralization of the NRC licensing process. This amendment extends to the five Regional Offices the same licensing authority for certain Federal activities as they now possess for non-Federal activities.

EFFECTIVE DATE: April 1, 1985.

FOR FURTHER INFORMATION CONTACT: Donald R. Chapell, Deputy Director, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: (301) 427-4152.

SUPPLEMENTARY INFORMATION: On May 27, 1982 (47 FR 23138), April 14, 1983 (48 FR 16030) (effective April 1, 1983), and May 9, 1984 (49 FR 19630) the Nuclear Regulatory Commission (NRC) published rules decentralizing most domestic licensing of nuclear materials. The NRC is amending its regulations to include certain Federal licensees in its decentralization program. Revisions to 10 CFR 30.6, 40.5, and 70.5 require certain Federal facilities with licenses issued pursuant to 10 CFR Part 30 through 35, 40, and 70 to contact the appropriate Regional office, rather than NRC Headquarters offices, for license applications, renewals, and revisions. This action now incorporates into the Regional materials licensing programs these Federal facility licensees.

The only Federal licensees not affected by this action are the United States Air Force and United States Navy. Their submittals under Parts 30 through 35, 40, and 70 will be sent to the Office of Nuclear Material Safety and Safeguards (NMSS). These licensees have not been included because they are currently in the process of submitting proposals for "broad" materials licenses with the NRC, which would, if approved, consolidate over one hundred individual licenses into one license each. Following these consolidations, it is intended that the licensing authority for the Air Force and the Navy also will be extended to the appropriate Regions.

This action also adds another item to the list of exceptions to the authority delegated to the Regions under the decentralization program. This exception, included as paragraph (b)(1)(v) in 30.6, 40.5 and 70.5, codifies current practice requiring NMSS to review new uses or techniques for use of nuclear material.

These amendments apply to NRC licensees and applicants in non-Agreement States, Guam, Puerto Rico, the Virgin Islands, and the District of Columbia, and to NRC Federal licensees and applicants wherever they are located within the NRC's jurisdiction except for the United States Air Force and Navy. Delegations of authority to the Regional Administrators are contained in NRC Manual Chapter 0128. The changes to §§ 30.6, 40.5, and 70.5 are nonsubstantive amendments. The revised sections indicate the type of licensing authority delegated to Regional Administrators.

Since these are minor, procedural amendments relating to agency organization and management, notice, opportunity for comment and a delay of effective date are not required by the Administrative Procedure Act under 5 U.S.C. 553.

Environmental Impact—Categorical Exclusion

The NRC has determined that this final rule is the type of action described in categorical exclusion 10 CFR 51.22(c)(3)(i). Accordingly, pursuant to 10 CFR 51.22(b), neither an environmental impact statement nor an environmental assessment has been prepared for this final rule.

Paperwork Reduction Act Statement

This final rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). Existing requirements were approved by the Office of Management and Budget approval numbers 3150-0017 for Part 30, 3150-0016 for Part 31, 3150-0001 for Part 32, 3150-0015 for Part 33, 3150-0007 for Part 34, 3150-0010 for Part 35, 3150-0020 for Part 40, and 3150-0009 for Part 70.

List of Subjects

10 CFR Part 30

Byproduct material, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Penalty, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 40

Government contracts, Hazardous materials-transportation, Nuclear materials, Penalty, Reporting and recordkeeping requirements, Source material, and Uranium.

10 CFR Part 70

Hazardous materials-transportation, Nuclear materials, Packaging and containers, Penalty, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Security measures, Special nuclear material.

Under the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552, the following amendments to 10 CFR Parts 30, 40, and 70 are published as a document subject to codification.

PART 31

GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL[†]

Sec.

31.1 Purpose and scope.
31.2 Terms and conditions.
31.3 Certain devices and equipment.
31.4 Information collection requirements: OMB approval.
31.5 Certain measuring, gauging or controlling devices.
31.6 General license to install devices generally licensed in § 31.5.
31.7 Luminous safety devices for use in aircraft.
31.8 Americium-241 in the form of calibration or reference sources.
31.9 General license to own byproduct material.
31.10 General license for strontium-90 in ice detection devices.
31.11 General license for use of byproduct materials for certain in vitro clinical or laboratory testing.

Authority: Secs. 81, 161, 183, 68 Stat. 935, 948, 954, as amended; 42 U.S.C. 2111, 2201, 2233. For the purposes of sec. 223, 68 Stat. 958, as amended; 42 U.S.C. 2273, 31.5(d)(5), 31.6(a) and 31.11(e) issued under sec. 161 o., 68 Stat. 950, as amended; 42 U.S.C. 2201(o), unless otherwise noted.

§ 31.1 Purpose and scope.

This part establishes general licenses for the possession and use of byproduct material contained in certain items and a general license for ownership of byproduct material. Part 30 of this chapter also contains provisions applicable to the subject matter of this part.

35 FR 6425

§ 31.2 Terms and conditions.

(a) The general licenses provided in this part are subject to the provision of §§ 30.14(d), 30.34(a) to (e), 30.41, 30.51 to 30.63 and Parts 19, 20, and 21 of this chapter[1] unless indicated otherwise in the language of the general license.

43 FR 6915

§ 31.3 Certain devices and equipment.

A general license is hereby issued to transfer receive, acquire, own, possess and use byproduct material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with the specifications contained in a specific license issued to him by the Commission.

(a) *Static elimination device.* Devices designed for use as static eliminators which contain, as a sealed source or sources, byproduct material consisting of a total of not more than 500 microcuries of polonium-210 per device.

(b) [Deleted 34 FR 6651.]

(c) [Deleted 35 FR 3982.]

(d) *Ion generating tube.* Devices designed for ionization of air which contain, as a sealed source or sources, byproduct material consisting of a total of not more than 500 microcuries of polonium-210 per device or of a total of not more than 50 millicuries of hydrogen-3 (tritium) per device.

30 FR 8185

§ 31.4 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). OMB has approved the information collection requirements contained in this part under control number 3150-0016.

(b) The approved information collection requirements contained in this part appear in §§ 31.5, 31.8, and 31.11.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In § 31.11. Form NRC-483 is approved under control number 3150-0038.

49 FR 21699

§ 31.5 Certain measuring, gauging or controlling devices.[2]

(a) A general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and Federal, State or local government agencies to acquire, receive, possess, use or transfer, in accordance with the provisions of paragraphs (b), (c) and (d) of this section, byproduct material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

39 FR 43531

(b) The general license in paragraph (a) of this section applies only to byproduct material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license issued pursuant to § 32.51 of this chapter or in accordance with the specifications contained in a specific license issued by an Agreement State which authorizes distribution of the devices to persons generally licensed by the Agreement State.

43 FR 6915

(c) Any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to the general license in paragraph (a) of this section:

(1) Shall assure that all labels affixed to the device at the time of receipt and bearing a statement that removal of the label is prohibited are maintained thereon and shall comply with all instructions and precautions provided by such labels;

(2) Shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label; however;

(i) devices containing only krypton need not be tested for leakage of radioactive material, and

(ii) devices containing only tritium or not more than 100 microcuries of other beta and/or gamma emitting material or

39 FR 43531

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[1] Attention is directed particularly to the provisions of the regulations in Part 20 of this chapter which relate to the labeling of containers.

[2] Persons possessing byproduct material in devices under the general license in § 31.5 before Jan. 15, 1975 may continue to possess, use or transfer that material in accordance with the requirements of § 31.5 in effect on Jan. 14, 1975.

READEX FICHE

10 microcuries of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;

(3) Shall assure that the tests required by paragraph (c)(2) of this section and other testing, installation, servicing, and removal from installation involving the radioactive materials, its shielding or containment, are performed:

(i) in accordance with the instructions provided by the labels; or

(ii) by a person holding a specific license pursuant to Parts 30 and 32 of this chapter or from an Agreement State to perform such activities;

(4) Shall maintain records showing compliance with the requirements of paragraphs (c)(2) and (c)(3) of this section. The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing, testing, installation, servicing, and removal from installation concerning the radioactive material, its shielding or containment.

Records of tests for leakage of radioactive material required by paragraph (c)(2) of this section shall be maintained for one year after the next required leak test is performed or until the sealed source is transferred or disposed of. Records of tests of the on-off mechanism and indicator, required by paragraph (c)(2) of this section, shall be maintained for one year after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed of. Records which are required by paragraph (c)(3) of this section shall be maintained for a period of two years from the date of the recorded event or until the device is transferred or disposed of.

(5) Upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 microcurie or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding a specific license pursuant to Parts 30 and 32 of this chapter or from an Agreement State to repair such devices, or disposed of by transfer to a person authorized by a specific license to receive the byproduct material contained in the device and, within 30 days, furnish to the Director of the appropriate Nuclear Regulatory Commission Inspection and Enforcement Regional Office listed in Appendix D of Part 20 of this chapter, a report containing a brief description of the event and the remedial action taken;

(6) Shall not abandon the device containing byproduct material;

(7) Shall not export the device containing byproduct material except in accordance with Part 110 of this chapter;

(8) Except as provided in paragraph (c)(9) of this section, shall transfer or dispose of the device containing byproduct material only by transfer to a person holding a specific license pursuant to Parts 30 and 32 of this chapter or from an Agreement State, to receive the device and within 30 days after transfer of a device to a specific licensee shall furnish to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, a report containing identification of the device by manufacturer's name and model number and the name and address of the person receiving the device. No report is required if the device is transferred to the specific licensee in order to obtain a replacement device;

(9) Shall transfer the device to another general licensee only:

(i) Where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of this section and any safety documents identified in the label of the device and within 30 days of the transfer, report to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, the manufacturer's name and model number of device transferred, the name and address of the transferee, and the name and/or position of an individual who may constitute a point of contact between the Commission and the transferee; or

(ii) Where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee.

(10) Shall comply with the provisions of §§ 20.402 and 20.403 of this chapter for reporting radiation incidents, theft or loss of licensed material, but shall be exempt from the other requirements of Parts 19, 20, and 21 of this chapter.

(d) The general license in paragraph (a) of this section does not authorize the manufacture or import of devices containing byproduct material.

§ 31.6 General license to install devices generally licensed in § 31.5.

Any person who holds a specific license issued by an Agreement State authorizing the holder to manufacture, install, or service a device described in § 31.5 within such Agreement State is hereby granted a general license to install and service such device in any non-Agreement State and a general license to install and service such device in offshore waters, as defined in § 150.3(f) of this chapter: *Provided,* That:

(a) [Deleted 39 FR 43531.]

(b) The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the Agreement State.

(c) Such person assures that any labels required to be affixed to the device under regulations of the Agreement State which licensed manufacture of the device bear a statement that removal of the label is prohibited.

(d) [Deleted 39 FR 43531.]

§ 31.7 Luminous safety devices for use in aircraft.

(a) A general license is hereby issued to own, receive, acquire, possess, and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided each device contains not more than 10 curies of tritium or 300 millicuries of promethium-147 and that each device has been manuactured, assembled or initially transferred in accordance with a license issued under the provisions of § 32.53 of this chapter or manufactured or assembled in accordance with a specific license issued by an Agreement State which authorizes manufacture or assembly of the device for distribution to persons generally licensed by the Agreement State.

(b) Persons who own, receive, acquire, possess or use luminous safety devices pursuant to the general license in this section are exempt from the requirements of Parts 19, 20, and 21 of this chapter, except that they shall comply with the provisions of §§ 20.402 and 20.403 of this chapter.

(c) This general license does not authorize the manufacture, assembly, repair or import of luminous safety devices containing tritium or promethium-147.

43 FR 6915

(d) This general license does not authorize the export of luminous safety devices containing tritium or promethium-147.

30 FR 8185

(e) This general license does not authorize the ownership, receipt, acquisition, possession or use of promethium-147 contained in instrument dials.

§ 31.8 Americium-241 in the form of calibration or reference sources.

(a) A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use and transfer, in accordance with the provisions of paragraphs (b) and (c) of this section, americium-241 in the form of calibration or reference sources:

(1) Any person in a non-Agreement State who holds a specific license issued pursuant to this chapter which authorizes him to receive, possess, use and transfer byproduct material, source material, or special nuclear material; and

(2) Any Government agency, as defined in § 30.4(g) of this chapter, which holds a specific license issued pursuant to this chapter which authorizes it to receive, possess, use and transfer byproduct material, source material, or special nuclear material.

43 FR 6915

(b) The general license in paragraph (a) of this section applies only to calibration or reference sources which have been manufactured or initially transferred in accordance with the specifications contained in a specific license issued pursuant to § 32.57 of this chapter or in accordance with the specifications contained in a specific license issued to the manufacturer by an Agreement State which authorizes manufacture of the sources for distribution to persons generally licensed by the Agreement State.

42 FR 28891

(c) The general license in paragraph (a) of this section is subject to the provisions of §§ 30.14(d), 30.34 (a) to (e), and 30.51 to 30.63 of this chapter, and to the provisions of Parts 19, 20, and 21 of this chapter. In addition, persons who own, receive, acquire, possess, use and transfer one or more calibration or reference sources pursuant to this general license:

30 FR 8185

(1) Shall not possess at any one time, at any one location of storage or use, more than 5 microcuries of americium-241 in such sources;

(2) Shall not receive, possess, use or transfer such source unless the source, or the storage container, bears a label which includes the following statement or a substantially similar statement which contains the information called for in the following statement: **

43 FR 6915

> **The receipt, possession, use and transfer of this source, Model ______, Serial No.____, are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.**
>
> CAUTION – RADIOACTIVE MATERIAL – THIS SOURCE CONTAINS AMERICIUM-241. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.
>
> ______________________________
>
> (Name of manufacturer or initial transferor)

30 FR 8185

(3) Shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license pursuant to this chapter or from an Agreement State to receive the source.

(4) Shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241 which might otherwise escape during storage.

(5) Shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

(d) This general license does not authorize the manufacture or import of calibration or reference sources containing americium-241.

(e) This general license does not authorize the export of calibration or reference sources containing americium-241.

§ 31.9 General license to own byproduct material.

A general license is hereby issued to own byproduct material without regard to quantity. Notwithstanding any other provision of this chapter, a general licensee under this paragraph is not authorized to manufacture, produce, transfer, receive, possess, use, import or export byproduct material, except as authorized in a specific license.

43 FR 6915

§ 31.10 General license for strontium-90 in ice detection devices.

(a) A general license is hereby issued to own, receive, acquire, possess, use, and transfer strontium-90 contained in ice detection devices, provided each device contains not more than fifty microcuries of strontium-90 and each device has been manufactured or initially transferred in accordance with the specifications contained in a license issued pursuant to § 32.61 of this chapter or in accordance with the specifications contained in a specific license issued to the manufacturer by an Agreement State which authorizes manufacture of the ice detection devices for distribution to persons generally licensed by the Agreement State.

30 FR 9904

(b) Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices pursuant to the general license in paragraph (a) of this section:

(1) Shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating, to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license pursuant to Parts 30 and 32 of this chapter or from an Agreement State to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of § 20.301 of this chapter;

(2) Shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon;

42 FR 28891

(3) Are exempt from the requirements of Parts 19, 20, and 21 of this chapter except that such persons shall comply with the provisions of §§ 20.301, 20.402, and 20.403 of this chapter.

30 FR 9904

(c) This general license does not authorize the manufacture, assembly, disassembly, repair, or import of strontium-90 in ice detection devices.

44 FR 50324

§ 31.11 General license for use of byproduct material for certain in vitro clinical or laboratory testing.

(a) A general license is hereby issued to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital to receive, acquire, possess, transfer, or use, for any of the following stated tests, in accordance with the provisions of paragraphs (b), (c), (d), (e), and (f) of this section, the following byproduct materials in prepackaged units:

**Sources generally licensed under this section prior to January 19, 1975, may bear labels authorized by the regulations in effect on January 1, 1975.

(1) Iodine-125, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(2) Iodine-131, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

33 FR 16553

(3) Carbon-14, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

38 FR 34110

(4) Hydrogen-3 (tritium), in units not exceeding 50 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(5) Iron-59, in units not exceeding 20 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings, or animals.

39 FR 26143

(6) Selenium-75, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human being or animals.

42 FR 21604

(7) Mock Iodine–125 reference or calibration sources, in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

42 FR 26986

(b) No person shall receive, acquire, possess, use, or transfer byproduct material pursuant to the general license established by paragraph (a) of this section until he has filed form NRC-483, "Registration Certificate-In Vitro Testing with Byproduct Material Under General License," with the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and received from the Commission a validated copy of Form NRC-483 with registration number assigned or until he has been authorized pursuant to § 35.14 (c) of this chapter to use byproduct material under the general license in this § 31.11.

41 FR 16445

41 FR 16446

The registrant shall furnish on Form NRC-483 the following information and such other information as may be required by that form:

(1) Name and address of the registrant;

(2) The location of use; and

(3) A statement that the registrant has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with byproduct materials as authorized under the general license in paragraph (a) of this section, and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the byproduct materials.

33 FR 16553

(c) A person who receives, acquires, possesses, or uses byproduct material pursuant to the general license established by paragraph (a) of this section shall comply with the following:

(1) The general licensee shall not possess at any one time, pursuant to the general license in paragraph (a) of this section, at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, and/or iron-59 in excess of 200 microcuries.

42 FR 21604

(2) The general licensee shall store the byproduct material, until used, in the original shipping container or in a container providing equivalent radiation protection.

(3) The general licensee shall use the byproduct material only for the uses authorized by paragraph (a) of this section.

(4) The general licensee shall not transfer the byproduct material except by transfer to a person authorized to receive it by a license pursuant to this chapter or from an Agreement State, nor transfer the byproduct material in any manner other than in the unopened, labeled shipping container as received from the supplier.

33 FR 16553

(5) The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in paragraph (a) (7) of this section as required by § 20.301 of this chapter.

42 FR 26986

(d) The general licensee shall not receive, acquire, possess, or use byproduct material pursuant to paragraph (a) of this section:

44 FR 50324

(1) Except as prepackaged units which are labeled in accordance with the provisions of a specific license issued under the provisions of § 32.71 of this chapter or in accordance with the provisions of a specific license issued by an Agreement State that authorizes manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), selenium-75, iron-59, or Mock Iodine-125 for distribution to persons generally licensed by the Agreement State.

42 FR 26986

(2) Unless the following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

> This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.
>
> ______________________________
>
> (Name of Manufacturer)

44 FR 50804

[Note removed 49 FR 19623]

33 FR 16553

(e) The registrant possessing or using byproduct materials under the general license of paragraph (a) of this section shall report in writing to the Director of Nuclear Material Safety and Safeguards any changes in the information furnished by him in the "Registration Certificate—In Vitro Testing With Byproduct Material Under General License," Form NRC-483. The report shall be furnished within 30 days after the effective date of such change.

42 FR 28891

(f) Any person using byproduct material pursuant to the general license of paragraph (a) of this section is exempt from the requirements of Parts 19, 20, and 21 of this chapter with respect to byproduct materials covered by that general license, except that such persons using the Mock Iodine-125 described in paragraph (a) (7) of this section shall comply with the provisions of §§ 20.301, 20.402, and 20.403 of this chapter.

§ 31.100 [Deleted 36 FR 16898.]

PART 31

GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

PROPOSED RULE MAKING

50 FR 30616
Published 7/26/85
Comment period expires 11/18/85

Medical Use of Byproduct Material

See Part 35 Proposed Rule Making

UNITED STATES NUCLEAR REGULATORY COMMISSION

RULES and REGULATIONS

TITLE 10, CHAPTER 1, CODE OF FEDERAL REGULATIONS—ENERGY

PART 31 GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

STATEMENTS OF CONSIDERATION

27 FR 5905
Published 6/22/62
Effective 6/22/62

See Part 20 Statements of Consideration

30 FR 8185
Published 6/26/65
Effective 8/25/65

See Part 30 Statements of Consideration.

30 FR 9904
Published 8/10/65
Effective 9/9/65

General License for Strontium 90 in Ice Detection Devices

On April 14, 1965, the Commission published in the FEDERAL REGISTER (30) F.R. 4764) proposed amendments of its regulation, "Licensing of Byproduct Material," 10 CFR Part 30, which would (a) provide a general license for fifty microcuries of strontium 90 when contained in an ice detection device and (b) set out requirements for Commission issuance of specific licenses for the manufacture or import of the ice detection devices.

All interested persons were invited to submit written comments and suggestions for consideration in connection with the proposed amendment within 60 days after publication in the FEDERAL REGISTER. No adverse comments or comments suggesting changes were received. Except for redesignation of sections and other minor revisions to conform with the recodification of 10 CFR Part 30, as published in the FEDERAL REGISTER June 26, 1965 (30 F.R. 8185) the text of the amendments set out below is identical with the text of the proposed amendments published April 14, 1965.

Pursuant to the Atomic Energy Act of 1954, as amended, and the Administrative Procedure Act of 1946, the following amendments of Title 10, Chapter I, Code of Federal Regulations, Part 31 "General Licenses for Certain Quantities of Byproduct Material and Byproduct Material Contained in Certain Items," and Part 32 "Specific Licenses to Manufacture, Distribute, or Import Exempted and Generally Licensed Items Containing Byproduct Material," are published as a document subject to codification, to be effective thirty (30) days after publication in the FEDERAL REGISTER.

30 FR 10947
Published 8/24/65
Effective 9/23/65

Labeling and Installation Requirements for Certain Devices Under General License

On April 30, 1965, the Commission published in the FEDERAL REGISTER (30 F.R. 6118) proposed amendments of its regulation, "Licensing of Byproduct Material", 10 CFR Part 30, which would (a) modify labeling requirements for certain devices used under general license and (b) modify installation requirements for such devices. All interested persons were invited to submit written comments and suggestions for consideration in connection with the proposed amendment within sixty days after publication in the FEDERAL REGISTER. No comments were received.

Since the notice of proposed rule making was published, Part 30 has been recodified. The amendments set forth below will accordingly appear in new Part 31 "General Licenses for Certain Quantities of Byproduct Material and Byproduct Material Contained in Certain Items" and Part 32 "Specific Licenses to Manufacture, Distribute, or Import Exempted and Generally Licensed Items Containing Byproduct Material". Except for redesignation of sections and other minor revisions to conform to the recodification of 10 CFR Part 30, published in the FEDERAL REGISTER June 26, 1965 (30 F.R. 8185), the text of the amendments set out below is identical with the text of the proposed amendments published April 30, 1965.

Pursuant to the Atomic Energy Act of 1954 as amended, and the Administrative Procedure Act of 1946, the following amendments of Title 10, Chapter I, Parts 31 and 32, Code of Federal Regulations are published as a document subject to codification, to be effective thiry (30) days after publication in the FEDERAL REGISTER.

33 FR 6462
Published 4/27/68
Effective 5/27/68

Increase in Quantity Limit for Promethium-147 in Generally Licensed Luminous Aircraft Safety Devices

On September 21, 1967, the Atomic Energy Commission published in the Federal Register (32 F.R. 13331), in response to a petition for rule making filed by Minnesota Mining and Manufacturing Co., proposed amendments to its regulations 10 CFR Parts 31 and 32 which would increase the quantity limit of generally licensed promethium-147 in any single aircraft safety device from 100 millicuries to 300 millicuries.

Interested persons were invited to submit written comments and suggestions for consideration in connection with the proposed amendments within 30 days after publication of the notice of proposed rule making in the Federal Register. After full consideration of the matter, the Commission has adopted the proposed amendments. The text of the amendments set out below is identical with the text of the proposed amendments published September 21, 1967.

The amendment to § 31.7 of Part 31 increases the maximum quantity of generally licensed promethium-147 in any single aircraft safety device from 100 millicuries to 300 millicuries. Section 32.53 of Part 32, which contains requirements for specific licenses to manufacture or import aircraft safety devices containing promethium-147 for distribution to general licensees, has been amended to reflect the increase in the amount of promethium-147 permitted under the general license.

The Commission has concluded that increasing the maximum quantity limit to 300 millicuries will not result in unacceptable radiation exposures and will not endanger public health and safety. The radiation levels permitted from devices containing 300 millicuries of promethium-147 would remain the same as radiation levels now permitted from devices containing 100 millicuries of promethium-147 and, accordingly, there would be no increase in the exposures to persons during use of the intact devices.

An applicant for a license to manufacture or import luminous safety devices containing promethium-147 for use in aircraft is required to conduct prototype tests on the devices to demonstrate that it is unlikely that a device will be physically damaged or lose its containment capability even under conditions of severe abuse (10 CFR § 32.101). In addition, the petitioner has submitted information which demonstrates that even if shielding defects occur, they are not likely to cause a significant increase in radiation exposures.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter 1, Code of Federal Regulations, Parts 31 and 32, are published as a document subject to codification effective thirty (30) days after publication in the Federal Register.

33 FR 16553
Published 11/14/68
Effective 1/13/69

General License for Use of Iodine-125 or Iodine-131 for in Vitro Clinical or Laboratory Testing

On April 26, 1968, the Atomic Energy Commission published in the Federal Register (33 F.R. 6375) proposed amendments to 10 CFR Parts 31 and 32 of its regulations which would, respectively, (a) issue a general license to physicians, clinical laboratories, and hospitals for the possession and use of iodine-125 or iodine-131 for in vitro clinical or laboratory tests not involving administration to human beings or animals; and (b) establish requirements for specific licenses to manufacture or distribute these radioiodines for use in such tests.

Interested persons were invited to submit written comments and suggestions for consideration within 30 days after publication of the notice of proposed rule making in the Federal Register. After consideration of the comments and other factors involved, the Commission has adopted the proposed amendments. The text of the amendments set out below is identical with that of the proposed amendments published April 26, 1968, except that § 32.71(c)(1) has been modified to provide for labeling to indicate that the amount of radioactivity per prepackaged unit does not exceed 10 microcuries; and the number of the registration form required to be filed by the general licensee has been inserted.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to title 10, Chapter I, Code of Federal Regulations, Parts 31 and 32, are published as documents subject to codification, to be effective sixty (60) days after publication in the Federal Register.

35 FR 6425
Published 4/22/70
Effective 10/22/70

See Part 30 Statements of Consideration.

38 FR 22220
Published 8/17/73
Effective 9/17/73

MISCELLANEOUS AMENDMENTS TO CHAPTER

Notice is hereby given of the amendment of 10 CFR Parts 31, 34, 35, 40, 70, 115, and 150.

Concurrently with the publication of this notice, the Atomic Energy Commission is publishing a new part to its regulations, 10 CFR Part 19, Notices, Instructions and Reports to Workers; Inspections. Certain sections that formerly appeared in 10 CFR Part 20 have been transferred to 10 CFR Part 19. In 10 CFR Parts 31, 34, 35, 40, 70, 115, and 150, references to 10 CFR Part 20 are made. The amendments which follow add 10 CFR Part 19 where each reference to a transferred section of 10 CFR Part 20 is made.

Other sections of the new 10 CFR Part 19 provide options to workers concerning inspections of working conditions regulated by the Commission comparable to those that are afforded for working conditions regulated by the Department of Labor pursuant to the Occupation Safety and Health Act of 1970, as set out in 29 CFR Part 1903. The amendments to 10 CFR Parts 31, 35 and 40 which follow exempt certain holders of general licenses from the requirements of 10 CFR Part 19 as well as from 10 CFR Part 20. The amendment to 10 CFR Part 34 requires licensees to provide radiographers with copies of, and instruction in applicable sections of, 10 CFR Part 19 as well as 10 CFR Part 20. The amendments to 10 CFR Parts 70 and 150 subject certain general licensees under those parts to the provisions of 10 CFR Part 19 as well as to 10 CFR Part 20. The amendment to 10 CFR Part 115 subjects persons authorized to operate certain Commission-owned nuclear reactors to the provisions of 10 CFR Part 19 as well as 10 CFR Part 20.

Because these amendments relate solely to clarification and consistency with existing regulations, the Commission has found that notice of proposed rulemaking and public procedure thereon are unnecessary.

Accordingly, pursuant to the Atomic Energy Act of 1954, as amended, the following amendments of 10 CFR Parts 31, 34, 35, 40, 70, 115 and 150 of the Commission's regulations are published as a document subject to codification, to be effective on September 17, 1973.

38 FR 33968
Published 12/10/73
Effective 3/11/74

Transfer of Radioactive Material; Requirements

See Part 30 Statements of Consideration.

38 FR 34110
Published 12/11/73
Effective 1/10/74

General License for Use of Carbon-14 for In Vitro Clinical or Laboratory Testing

On September 26, 1973, the Atomic Energy Commission published in the Federal Register (38 FR 26813) proposed amendments of its regulations 10 CFR Parts 31 and 32 which would authorise any physician, clinical laboratory, or hospital to use carbon-14 in units not exceeding 10 microcuries each, in in vitro clinical or laboratory tests, subject to the conditions set out in § 31.11(b), (c), (d), (e), and (f).

All interested persons were invited to submit written comments and suggestions for consideration in connection with the proposed amendments by November 12, 1973. After consideration of the comments and other factors involved, the Commission has adopted the proposed amendments. The text of the amendments set out below is identical with the text of the proposed amendments published September 26, 1973.

Under the provisions of the general license, as amended, the general licensee may issue a purchase order on a standing basis for a supply of carbon-14 in prepackaged units to be delivered at any rate of shipment. Hospitals use vials containing 1.5 microcuries of carbon-14 in large numbers when operating an automated system for detecting bacteria in blood and other fluids.

The general license as amended in no way affects transactions involving exempt quantities subject to § 32.19, nor does it relax any radiological safety controls over the use of carbon-14 in in vitro clinical or laboratory tests.

The general licensee would be required to register with the Commission and receive an acknowledgement of his registration and a registration number before receiving carbon-14 pursuant to the general license. The objectives of the registration requirement are to (1) provide a means of identifying the general licensee, (2) provide assurance that the general licensee is aware of the terms and conditions of the general license prior to receipt of carbon-14 for use under the general license, and (3) facilitate communication with the general licensee.

As amended, § 32.71, which is intended to assure that general licensees receive properly packaged products which are labeled to identify the radioactive contents and to specify that use is restricted to in vitro clinical or laboratory tests, includes requirements for issuance of specific licenses to manufacture or distribute carbon-14 for use under the general license in § 31.11.

Pursuant to the Atomic Energy Act of 1954, as amended. and sections 552 and

553 of title 5 of the United States Code, the following amendments of Title 10, Chapter I, Code of Federal Regulations, Parts 31 and 32, are published as a document subject to codification.

39 FR 26143
Published 7/17/74
Effective 8/16/74 (Parts 31 & 32)
Effective 1/13/75 (Part 35)

Group Licensing for Certain Medical Uses

See Part 35 Statements of Consideration.

39 FR 43531
Published 12/16/74
Effective 1/15/75

Revision of General License for Industrial Devices

See Part 32 Statements of Consideration.

41 FR 16445
Published 4/19/76
Effective 4/19/76

Miscellaneous Changes to Chapter

See Part 20 Statements of Consideration.

41 FR 18300
Published 5/3/76
Effective 6/2/76

Preservation of Records

See Part 20 Statements of Consideration.

42 FR 21604
Published 4/28/77
Effective 5/31/77

PART 31—GENERAL LICENSES FOR BYPRODUCT MATERIAL

PART 32—SPECIFIC LICENSES TO MANUFACTURE, DISTRIBUTE, OR IMPORT CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

Addition to General License for In Vitro Diagnostic Products

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations to add selenium-75 to the list of radionuclides in the general license for medical laboratory use. This rule change, which was requested by Amersham Searle Corp., will reduce the cost of distribution of several products used for the diagnosis of disease.

EFFECTIVE DATE: May 31, 1977.

FOR FURTHER INFORMATION CONTACT: Edward Podolak, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (301–443–6910).

SUPPLEMENTARY INFORMATION: On February 7, 1977, the Nuclear Regulatory Commission (NRC) published a proposed rule (42 FR 7158) to amend its regulations: (1) § 31.11 to add selenium-75 to the list of radionuclides in the general license for in vitro diagnostic use, and (2) § 32.71 to add selenium-75 to the list of radionuclides manufactured and distributed for use under the in vitro general license. The public was invited to submit written comments on the proposed rule by March 24, 1977. No adverse comments were received. Therefore the text of § 31.11 and § 32.71 set out below is identical with the proposed amendment.

The general license in § 31.11 permits any physician, clinical laboratory, or hospital to receive, acquire, possess, transfer, or use iodine-125, iodine-131, carbon-14, hydrogen-3, and iron-59 for in vitro testing of body fluids such as blood and urine. In vitro tests are laboratory tests performed outside the human body.

Amersham/Searle Corporation of Arlington Heights, Illinois, filed a petition for rulemaking (PRM 31–1) with the NRC (by letter dated April 23, 1976) requesting the inclusion of selenium-75 in the § 31.11 general license. This notice of rulemaking responds to the request of Amersham/Searle Corp.

Under the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendments to title 10, Chapter I, Code of Federal Regulations, Parts 31 and 32 are published as a document subject to codification.

42 FR 26986
Published 5/26/77
Effective 6/27/77

PART 31—GENERAL LICENSES FOR BYPRODUCT MATERIAL

PART 32—SPECIFIC LICENSES TO MANUFACTURE, DISTRIBUTE, OR IMPORT CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

Addition to General License for In Vitro Diagnostic Products

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations to add Mock Iodine-125 to the list of radionuclides in the general license for medical laboratory use. This rule change, requested by The Nucleus of Oak Ridge, Tennessee, will benefit the medical patient by improving the data for the diagnosis of disease.

EFFECTIVE DATE: June 27, 1977.

FOR FURTHER INFORMATION CONTACT: Deborah A. Bozik, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (301–443–6911).

SUPPLEMENTARY INFORMATION: On March 24, 1977, the Nuclear Regulatory Commission (NRC) published a proposed rule (42 FR 15913) to amend its regulations: (1) § 31.11 to add Mock Iodine-125 to the list of radionuclides in the general license for in vitro diagnostic use; and (2) § 32.71 to add Mock Iodine-125 to the list of radionuclides manufactured and distributed for use under the in vitro general license. The public was invited to submit written comments on the proposed rule by May 9, 1977, and no comments were received. Therefore, the text of § 31.11 and § 32.71 set out below is identical with the proposed amendment.

The general license in. § 31.11 authorizes any physician, clinical laboratory or hospital to receive, acquire, possess, transfer or use iodine-125, iodine-131, carbon-14, hydrogen-3, selenium-75 and iron-59 for in vitro testing of body fluids. In vitro refers to laboratory tests performed outside of the human body.

The Nucleus, Inc., of Oak Ridge, Tennessee, filed a petition for rule making (PRM 31—2) with the NRC (by letter dated June 23, 1976) requesting the inclusion of Mock Iodine-125 in the general license in § 31.11. This notice of rule making responds to the request of the Nucleus, Inc.

Under the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Parts 31 and 32 are published as a document subject to codification.

42 FR 28891
Published 6/6/77
Effective 7/6/77; §§21.6, 21.21(a), and 21.51 effective 1/6/78
(7/6/77 effective date extended to 8/10/77)

Reports to the Commission Concerning Defects and Noncompliance

See Part 21 Statements of Consideration.

43 FR 6915
Published 2/17/78
Effective 5/3/78

Export and Import of Nuclear Facilities and Materials

See Part 110 Statements of Consideration.

44 FR 50324
Published 8/28/79
Effective 9/27/79

10 CFR Parts 31 and 32

Addition of Veterinarians to the In Vitro General License

AGENCY: U.S. Nuclear Regulatory Commission

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations to add veterinarians to the groups already authorized to use byproduct material under general license for clinical or laboratory testing done outside the body. The general license is useful for the regulation of a large number of identical or similar uses under circumstances in which the safety of the use is not highly dependent upon the competence of the user or when it is practical to identify a class of users who may be assumed to have the necessary qualifications. This action is in response to a petition for rulemaking.

EFFECTIVE DATE: September 27, 1979.

FOR FURTHER INFORMATION CONTACT: Deborah A. Bozik, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (Phone 301–443–5860).

SUPPLEMENTARY INFORMATION: On April 26, 1979, the Nuclear Regulatory Commission (NRC) published a proposed rule (44 FR 24570) to amend its regulations: (1) To authorize the addition of veterinarians as general licensees to § 31.11 of 10 CFR Part 31, the general license for use of byproduct material for certain *in vitro* (outside the body) clinical or laboratory testing; (2) to add veterinarians to the group of those authorized to receive, acquire, possess and use byproduct material which is manufactured and distributed by persons holding a specific license in § 32.71 of 10 CFR Part 32. The public was invited to submit written comments on the proposed rule by June 25, 1979. Nineteen comments were received and seventeen of these approved the proposed rule without qualification. One commenter suggested that a one year changeover period starting from the date of the effective rule should be given to manufacturers of *in vitro* reagents so that manufacturers could use up old stocks of labels and brochures printed prior to this effective rule. The commenter stated that it would be very expensive to destroy all existing labels and brochures simply to add the phrase "veterinarians in the practice of veterinary medicine" to the labels. NRC agrees and this suggestion has been incorporated into the effective rule so that labels authorized by the regulations in effect on the day before the date of this effective rule may be used until one year from the date of the effective rule.

The same commenter suggested that this general license be extended to include other categories of persons or institutions and gave as examples blood banks, poison control centers, forensic laboratories and drug abuse clinics. The NRC does not agree because one of the criteria for issuing a general license is that the user group is well defined with respect to training in ionizing radiation. Physicians and veterinarians fulfill this criterion; however, blood banks, poison control centers, forensic laboratories and drug abuse clinics do not necessarily fulfill this criterion. In discussing this point with the commenter, he stated that this was not a critical problem at this time since these groups could apply for specific licenses to operate.

Another commenter questioned the choice of the proposed wording which limited a veterinarian to "the practice of veterinary medicine." The staff believes that limiting the veterinarian's use of *in vitro* kits to the practice of veterinary medicine is essential because if someone other than a physician sets up a clinical laboratory, the NRC wants that person to apply for a specific license so that their qualifications can be reviewed. The NRC contacted the commenter and he accepted our explanation. The NRC further discussed with him the point that the phrase "veterinarians in the practice of veterinary medicine" does not exclude veterinary research in which this commenter was involved.

Currently, the veterinarian must use byproduct material under a specific license. A specific license is required for any activity in which the safety of the proposed use is highly dependent upon such factors as the qualifications of the particular licensee and the unique characteristics of the use. Currently, physicians use byproduct material for the same type of tests as the veterinarians; however, physicians use it under a general license. A general license is effective without the filing of applications with the Commission or the issuance of licensing documents to particular persons.

Under the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Parts 31 and 32 are published as a document subject to codification.

46 FR 44149
Published 9/3/81
Effective 10/5/81

NRC's Jurisdiction Over Persons Using Byproduct, Source or Special Nuclear Materials in Certain Offshore Waters

See Part 150 Statements of Consideration

➤ **49 FR 19623**
Published 5/9/84
Effective 5/9/84

Information Collection Requirements; Display of OMB Control Numbers

See Part 0 Statements of Consideration

➤ **49 FR 21699**
Published 5/23/84
Effective 5/23/84

Information Collection Requirements, Display of OMB Control Numbers

See Part 0 Statements of Consideration

PART 32

SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

Sec.
32.1 Purpose and scope.
32.2 Definitions.
32.8 Information collection requirements: OMB approval.

Subpart A—Exempt Concentrations and Items

32.11 Introduction of byproduct material in exempt concentrations into products or materials, and transfer of ownership or possession: requirements for license.
32.12 Same: records and material transfer reports.
32.13 Same: prohibition of introduction.
32.14 Certain items containing byproduct material; requirements for license to apply or initially transfer.
32.15 Same: quality assurance, prohibition of transfer, and labeling.
32.16 Certain items containing byproduct material: Records and reports of transfer.
32.17 Resins containing scandium-46 and designed for sand-consolidation in oil wells: requirements for license to manufacture, or initially transfer for sale or distribution.
32.18 Manufacture, distribution and transfer of exempt quantities of byproduct material: requirements for license.
32.19 Same: conditions of licenses.
32.20 Same: Records and material transfer reports.
32.22 Self-luminous products containing tritium, krypton-85 or promethium-147: requirements for license to manufacture, process, produce, or initially transfer.
32.23 Same: safety criteria.
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32.25 Conditions of licenses issued under § 32.22: quality control, labeling, and reports of transfer.
32.26 Gas and aerosol detectors containing byproduct material: requirements for license to manufacture, process, produce, or initially transfer.
32.27 Same: safety criteria.
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32.40 Schedule A—Prototype tests for automobile lock illuminators.

Subpart B—Generally Licensed Items

Sec.
32.51 Byproduct material contained in devices for use under § 31.5; requirements for license to manufacture or initially transfer.
32.51a Same: conditions of licenses.
32.52 Same: material transfer reports and records.
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32.54 Same: labeling of devices.
32.55 Same: quality assurance; prohibition of transfer.
32.56 Same: material transfer reports.
32.57 Calibration or reference sources containing americium-241: requirements for license to manufacture or initially transfer.
32.58 Same: labeling of devices.
32.59 Same: leak testing of each source.
32.60 [Reserved]
32.61 Ice detection devices containing strontium-90; requirements for license to manufacture or initially transfer.
32.62 Same: quality assurance; prohibition of transfer.
32.70 Manufacture and distribution of byproduct materials for medical use under general license.
32.71 Manufacture and distribution of byproduct material for certain in vitro clinical or laboratory testing under general license.
32.72 Manufacture and distribution of radiopharmaceuticals containing byproduct material for medical use under group licenses.
32.73 Manufacture and distribution of generators or reagent kits for preparation of radiopharmaceuticals containing byproduct material.
32.74 Manufacture and distribution of sources or devices containing byproduct material for medical use.
32.101 Schedule B—Prototype tests for luminous safety devices for use in aircraft.
32.102 Schedule C—Prototype tests for calibration or reference sources containing americium-241.
32.103 Schedule D—Prototype tests for ice detection devices containing strontium 90.

Subpart C—Quality Control Sampling Procedures

32.110 Acceptance sampling procedures under certain specific licenses.

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); secs. 32.13, 32.15 (a), (c) and (d), 32.19, 32.25 (a) and (b), 32.29 (a) and (b), 32.54, 32.55 (a), (b) and (d), 32.58, 32.59, and 32.62 are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and secs. 32.12, 32.16, 32.20, 32.25(c), 32.29(c), 32.51a, 32.52 and 32.56 are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

§ 32.1 Purpose and scope.

(a) This part prescribes requirements for the issuance of specific licenses to persons who manufacture, or initially transfer items containing byproduct material for sale or distribution to (1) persons exempted from the licensing requirements of Part 30 of this chapter, or (2) persons generally licensed under Part 31 or 35 of this chapter. This part also prescribes certain regulations governing holders of such licenses. In addition, this part prescribes requirements for the issuance of specific licenses to persons who introduce byproduct material into a product or material owned by or in the possession of the licensee or another and regulations governing holders of such licenses.

43 FR 6915

(b) The provisions and requirements of this part are in addition to, and not in substitution for, other requirements of this chapter. In particular, the provisions of Part 30 of this chapter apply to applications and licenses subject to this part.

30 FR 8185

§ 32.2 Definitions.

As used in this part:

(a) "Dose commitment" means the total radiation dose to a part of the body that will result from retention in the body of radioactive material. For purposes of estimating the dose commitment, it is assumed that from the time of intake the period of exposure to retained material will not exceed 50 years.

34 FR 6653

(b) Lot Tolerance Percent Defective means, expressed in percent defective, the poorest quality in an individual inspection lot that should be accepted.

39 FR 22129

§ 32.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). OMB has approved the information collection requirements contained in this part under control number 3150–0001.

(b) The approved information collection requirements contained in this part appear in §§ 32.12, 32.14, 32.15, 32.16, 32.17, 32.18, 32.19, 32.20, 32.22, 32.25, 32.26, 32.29, 32.51, 32.51a, 32.52, 32.53, 32.54, 32.56, 32.57, 32.58, 32.61, 32.70, 32.71, 32.72, 32.73, and 32.74.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In § 32.11, Form NRC–313I is approved under control number 3150–0042.

49 FR 19623

Subpart A—Exempt Concentrations and Items

§ 32.11 Introduction of byproduct material in exempt concentrations into products or materials, and transfer of ownership or possession: requirements for license.

49 FR 19623

An application for a specific license on Form NRC-313 authorizing the introduction of byproduct material into a product or material owned by or in the possession of the licensee or another and the transfer of ownership or possession of the product or material containing the byproduct material will be approved if the applicant:

30 FR 8185

(a) Satisfies the general requirements specified in § 30.33 of this chapter;

(b) Provides a description of the product or material into which the byproduct material will be introduced, intended use of the byproduct material and the product or material into which it is introduced, method of introduction, initial concentration of the byproduct material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material, and estimated concentration of the radioisotopes in the product or material at the time of transfer; and

(c) Provides reasonable assurance that the concentrations of byproduct material at the time of transfer will not exceed the concentrations in § 30.70 of this chapter, that reconcentration of the byproduct material in concentrations exceeding those in § 30.70 is not likely, that use of lower concentrations is not feasible, and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

§ 32.12 Same: records and material transfer reports.

48 FR 12331

(a) Each person licensed under § 32.11 shall maintain records of transfer of material and file a report with the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, with a copy to the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter.

(b) The report must identify the—

(1) Type and quantity of each product or material into which byproduct material has been introduced during the reporting period;

(2) Name and address of the person who owned or possessed the product or material, into which byproduct material has been introduced, at the time of introduction;

(3) The type and quantity of radionuclide introduced into each product or material; and

(4) The initial concentrations of the radionuclide in the product or material at time of transfer of the byproduct material by the licensee.

(c) The licensee shall file the report within 30 days following—

(1) Five years after filing the preceding report; or

(2) Filing an application for renewal of the license under § 30.37 * ; or

(3) Notifying the Commission under § 30.34(f) of the licensee's decision to permanently discontinue activities authorized under the license issued under § 32.11.

(d) The report must cover the period between the filing of the preceding report and the occurrence specified in paragraphs (c) (1), (2), or (3) of this section. If no transfers of byproduct material have been made under § 32.11 during the reporting period, the report shall so indicate.

(e) The licensee shall maintain the record of a transfer for a period of one year after the event is included in a report to the Commission.

§ 32.13 Same: prohibition of introduction.

30 FR 8185

No person may introduce byproduct material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under § 30.14 of this chapter or equivalent regulations of an Agreement State, except in accordance with a license issued pursuant to § 32.11 or the general license provided in § 150.20 of this chapter.

§ 32.14 Certain items containing byproduct material; requirements for license to apply or initially transfer.

43 FR 6915

An application for a specific license to apply byproduct material to, or to incorporate byproduct material into, the products specified in § 30.15 of this chapter or to initially transfer for sale or distribution such products containing byproduct material for use pursuant to § 30.15 of this chapter will be approved if:

31 FR 5315

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter;

34 FR 6651

(b) The applicant submits sufficient information regarding the product pertinent to evaluation of the potential radiation exposure, including:

(1) Chemical and physical form and maximum quantity of byproduct material in each product;

(2) Details of construction and design of each product;

(3) The method of containment or binding of the byproduct material in the product;

(4) Procedures for and results of prototype testing to demonstrate that the material will not become detached from the product and that the byproduct material will not be released to the environment under the most severe conditions likely to be encountered in normal use of the product:

(5) Quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet;

43 FR 6915

(6) The proposed method of labeling or marking each unit, except timepieces or hands or dials containing tritium or promethium-147, and its container with the identification of the manufacturer or initial transferor of the product and the byproduct material in the product;

34 FR 6651

(7) For products for which limits on levels of radiation are specified in § 30.15 of this chapter, the radiation level and the method of measurement;

(8) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the product.

(c) Each product will contain no more than the quantity of byproduct material specified for that product in § 30.15 of this chapter. The levels of radiation from each product containing byproduct material will not exceed the limits specified for that product in § 30.15 of this chapter.

(d) The Commission determines that:

(1) The method of containment or binding of the byproduct material in the product is such that the radioactive material will not be released or be removed from the product under the most severe conditions which are likely to be encountered in normal use and handling. Tritium will be considered to be properly bound to dials, hands, and pointers if there is no visible flaking or chipping and the total loss of tritium does not exceed 5 percent of the total tritium when prototype dials, hands, and pointers are subjected to the following tests in the order specified below.

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*Correction 48 FR 14863

(i) Attachment of dials to a vibrating fixture and vibration at a rate of not less than 26 cycles per second and a vibration acceleration of not less than 2G for a period of not less than one hour; and

(ii) Attachment of the hub ends of the hands or pointers to a clamp and bending of hands or pointers over a 1-inch diameter cylinder; and

(iii) Total immersion of the dials, hands and pointers used in the tests described in paragraphs (d)(1)(i) and (ii) of this section in 100 milliliters of water at room temperature for a period of 24 consecutive hours and analysis of the test water for its radioactive material content by liquid scintillation counting or other equally sensitive method.

(2) The product has been subjected to and meets the requirements of the prototype tests. Prototype tests for automobile lock illuminators are prescribed by § 32.40, Schedule A.

31 FR 5315

§ 32.15 Same: quality assurance, prohibition of transfer, and labeling.

(a) Each person licensed under § 32.14 shall:

(1) Maintain quality assurance practices in the manufacture of the part or product, or the installation of the part into the product;

(2) Subject inspection lots to such testing as may be required as a condition of the license issued under § 32.14 taking a random sample of the size required by the tables in § 32.110, and for Lot Tolerance Percent Defective of 5.0 percent, accept or reject inspection lots in accordance with the directions of § 32.110; and

(3) Visually inspect each unit, except electron tubes containing byproduct material, in inspection lots. Any unit which has an observable physical defect that could affect containment of the byproduct material shall be considered as a defective unit.

(b) An application for a license or for amendment of a license may include a description of procedures proposed as alternatives to those prescribed by paragraph (a)(2) of this part, and proposed criteria for acceptance under those procedures. The Commission will approve the proposed alternative procedures if the applicant demonstrates that the operating characteristic curve or confidence interval estimate for the alternative procedures provides a Lot Tolerance Percent Defective of 5.0 percent at the consumer's risk of 0.10.

(c) No person licensed under § 32.14 shall transfer to other persons for use under § 30.15 of this chapter or equivalent regulations of an Agreement State:

(1) Any part or product which has been tested and found defective under the criteria and procedures specified in the license issued under § 32.14, unless the defective units have been repaired or reworked and have then met such criteria as may be required as a condition of the license issued under § 32.14; or

(2) Any inspection lot which has been rejected as a result of the procedures in § 32.110 or alternative procedures in paragraph (b) of this section, unless the defective units have been sorted and removed or have been repaired or reworked and have then met such criteria as may be required as a condition of the license issued under § 32.14.

39 FR 22129

(d) Label or mark each unit, except timepieces or hands or dials containing tritium or promethium-147, and its container so that the manufacturer or initial transferor of the product and the byproduct material in the product can be identified.

43 FR 6915

§ 32.16 Certain items containing byproduct material: Records and reports of transfer.

(a) Each person licensed under § 32.14 or § 32.17 shall maintain records of transfer of material and report to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, with a copy to the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter.

48 FR 12331

(b) The report must include the following information on items transferred to other persons for use under § 30.15 or 30.16 of this chapter or equivalent regulations of an Agreement State—

48 FR 23383

(1) A description or identification of the type of each product;

(2) For each radionuclide in each type of product, the total quantity of the radionuclide; and

(3) The number of units of each type of product transferred during the reporting period.

(c) The licensee shall file the report within 30 days after—

(1) Five years after filing the preceding report; or

(2) Filing an application for renewal of the license under § 30.37; or

(3) Notifying the Commission under § 30.34(f) of the licensee's decision to permanently discontinue activities authorized under the license issued under § 32.14 or § 32.17.

(d) The report must cover the period between the filing of the preceding report and the occurrence specified in paragraphs (c) (1), (2), or (3) of this section. If no transfers of byproduct material have been made under § 32.14 or § 32.17 during the reporting period, the report must so indicate.

(e) The licensee shall maintain the record of a transfer for a period of one year after the event is included in a report to the Commission.

48 FR 12331

§ 32.17 Resins containing scandium-46 and designed for sand-consolidation in oil wells: requirements for license to manufacture, or initially transfer for sale or distribution.

An application for a specific license to manufacture, or initially transfer for sale or distribution, synthetic plastic resins containing scandium-46 for use pursuant to § 30.16 of this chapter will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter;

(b) The product is designed to be used only for sand-consolidation in oil wells;

(c) The applicant submits the following information:

(1) The general description of the product to be manufactured or initially transferred.

43 FR 6915

(2) A description of control procedures to be used to assure that the concentration of scandium-46 in the final product at the time of distribution will not exceed 1.4×10^{-3} microcurie/milliliter.

38 FR 29314

(d) Each container of such product will bear a durable, legible lable approved by the Commission, which contains the following information:

(1) The product name;

(2) A statement that the product contains radioactive scandium and is designed and manufactured only for sand-consolidation in oil wells;

(3) Instructions necessary for proper use; and

(4) The manufacturer's name.

32 FR 4241

§ 32.18 Manufacture, distribution and transfer of exempt quantities of byproduct material: requirements for license.

An application for a specific license to manufacture, process, produce, package, repackage, or transfer quantities of byproduct material for commercial distribution to persons exempt pursuant to § 30.18 of this chapter or the equivalent regulations of an Agreement State will be approved if:

43 FR 6915

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter: *Provided, however,* That the requirements of § 30.33(a) (2) and (3) of this chapter do not apply to an application for a license to transfer byproduct material manufactured, processed, produced, packaged, or repackaged pursuant to a license issued by an Agreement State;

(b) The byproduct material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being;

(c) The byproduct material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and

(d) The applicant submits copies of prototype labels and brochures and the Commission approves such labels and brochures.

35 FR 6425

§ 32.19 Same: conditions of licenses.

Each license issued under § 32.18 is subject to the following conditions:

(a) No more than 10 exempt quantities set forth in § 30.71, Schedule B of this chapter shall be sold or transferred in any single transaction. For purposes of this requirement, an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in § 30.71, Schedule B of this chapter, provided that the sum of such fractions shall not exceed unity.

(b) Each quantity of byproduct material set forth in § 30.71, Schedule B of this chapter shall be separately and individually packaged. No more than 10 such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to § 30.18 of this chapter. The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem per hour.

(c) The immediate container of each quantity or separately packaged fractional quantity of byproduct material shall bear a durable, legible label which (1) identifies the radioisotope and the quantity of radioactivity, and (2) bears the words "Radioactive Material."

(d) In addition to the labeling information required by paragraph (c) of this section, the label affixed to the immediate container, or an accompanying brochure, shall also (1) state that the contents are exempt from NRC or Agreement State licensing requirements; (2) bear the words "Radioactive Material—Not for Human Use—Introduction Into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or Into Products Manufactured for Commercial Distribution is Prohibited—Exempt Quantities Should Not be Combined"; and (3) set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.

43 FR 6915
35 FR 6425

§ 32.20 Same: Records and material transfer reports.

(a) Each person licensed under § 32.18 of this part shall maintain records of transfer of material identifying, by name and address, each person to whom byproduct material is transferred for use under § 30.18 of this chapter or the equivalent regulations of an Agreement State and stating the kinds and quantities of byproduct material transferred. The licensee shall maintain the record of a transfer for a period of one year after the event is included in a summary report to the Commission.

(b) The licensee shall file a summary report stating the total quantity of each isotope transferred under the specific license with the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, with a copy to the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter.

(c) The licensee shall file the summary report within 30 days following—

(1) Five years after filing the preceding report; or

(2) Filing an application for renewal of the license under § 30.37; or

(3) Notifying the Commission under § 30.34(f) of the licensee's decision to permanently discontinue activities authorized under the license issued under § 32.18.

(d) The report must cover the period between the filing of the preceding report and the occurrences specified in paragraphs (c)(1), (2), or (3) of this section. If no transfers of byproduct material have been made under § 32.18 during the reporting period, the report must so indicate.

48 FR 12331

§ 32.22 Self-luminous products containing tritium, krypton-85 or promethium-147: requirements for license to manufacture, process, produce, or initially transfer.

(a) An application for a specific license to manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, or to initially transfer such products for use pursuant to § 30.19 of this chapter or equivalent regulations of an Agreement State, will be approved if:

43 FR 6915

(1) The applicant satisfies the general requirements specified in § 30.33 of this chapter: *Provided, however,* That the requirements of § 30.33(a) (2) and (3) do not apply to an application for a license to transfer tritium, krypton-85, or promethium-147 in self-luminous products manufactured, processed, or produced pursuant to a license issued by an Agreement State.

(2) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, and conditions of handling, storage, use, and disposal of the self-luminous product to demonstrate that the product will meet the safety criteria set forth in § 32.23. The information should include:

(i) A description of the product and its intended use or uses.

(ii) The type and quantity of byproduct material in each unit.

(iii) Chemical and physical form of the byproduct material in the product and changes in chemical and physical form that may occur during the useful life of the product.

(iv) Solubility in water and body fluids of the forms of the byproduct material identified in paragraph (a)(2) (iii) and (xii) of this section.

(v) Details of construction and design of the product as related to containment and shielding of the byproduct material and other safety features under normal and severe conditions of handling, storage, use, and disposal of the product.

(vi) Maximum external radiation levels at 5 and 25 centimeters from any external surface of the product, averaged over an area not to exceed 10 square centimeters, and the method of measurement.

(vii) Degree of access of human beings to the product during normal handling and use.

(viii) Total quantity of byproduct material expected to be distributed in the product annually.

(ix) The expected useful life of the product.

34 FR 9025

(x) The proposed method of labeling or marking each unit with identification of the manufacturer or initial transferor of the product and the byproduct material in the product.

43 FR 6915

(xi) Procedures for prototype testing of the product to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, and disposal of the product.

(xii) Results of the prototype testing of the product, including any change in the form of the byproduct material contained in the product, the extent

34 FR 9025

to which the byproduct material may be released to the environment, any increase in external radiation levels, and any other changes in safety features.

(xiii) The estimated external radiation doses and dose commitments relevant to the safety criteria in § 32.23 and the basis for such estimates.

(xiv) A determination that the probabilities with respect to the doses referred to in § 32.23(d) meet the criteria of that paragraph.

(xv) Quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet.

(xvi) Any additional information, including experimental studies and tests, required by the Commission.

(b) Notwithstanding the provisions of paragraph (a) of this section, the Commission may deny an application for a specific license under this section if the end uses of the product cannot be reasonably foreseen.

34 FR 9025

§ 32.23 Same: safety criteria.

An applicant for a license under § 32.22 shall demonstrate that the product is designed and will be manufactured so that:

(a) In normal use and disposal of a single exempt unit, it is unlikely that the external radiation dose in any one year, or the dose commitment resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the product will exceed the dose to the appropriate organ as specified in Column I of the table in § 32.24 of this part.

(b) In normal handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, it is unlikely that the external radiation dose in any one year, or the dose commitment resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the product will exceed the dose to the appropriate organ as specified in Column II of the table in § 32.24.

(c) It is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the product from wear and abuse likely to occur in normal handling and use of the product during its useful life.

34 FR 9025

(d)[1] In use and disposal of a single exempt unit, or in handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, the probability is low that the containment, shielding, or other safety features of the product would fail under such circumstances that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column III of the table in § 32.24, and the probability is negligible that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column IV of the table in § 32.24.

34 FR 9329

§ 32.24 Same: table of organ doses.

Part of body	Column I (rem)	Column II (rem)	Column III (rem)	Column IV (rem)
Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	0.001	0.01	0.5	15
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	0.015	0.15	7.5	200
Other organs	0.003	0.03	1.5	50

43 FR 6915

§ 32.25 Conditions of licenses issued under § 32.22: quality control, labeling, and reports of transfer.

Each person licensed under § 32.22 shall:

(a) Carry out adequate control procedures in the manufacture of the product to assure that each production lot meets the quality control standards approved by the Commission;

(b) Label or mark each unit so that the manufacturer, processor, producer, or initial transferor of the product and the byproduct material in the product can be identified; and

48 FR 12331

(c) Maintain records and file reports with the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, with copies to the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter.

(1) The report must include the following information on products transferred to other persons for use under § 30.19 of this chapter or equivalent regulations of an Agreement State—

(i) A description or identification of the type of each product;

(ii) For each radionuclide in each type of product, the total quantity of the radionuclide; and

(iii) The number of units of each type of product transferred during the reporting period.

(2) The licensee shall file the report within 30 days following—

(i) Five years after filing the preceding report; or

(ii) Filing an application for renewal of the license under § 30.37; or

(iii) Notifying the Commission under § 30.34(f) of the licensee's decision to permanently discontinue activities authorized under the license issued under § 32.22.

(3) The report must cover the period between the filing of the preceding report and the occurrences specified in paragraphs (c)(2)(i), (ii), or (iii) of this section. If no transfers of byproduct material have been made under 32.22 during the reporting period, the report must so indicate.

(4) The licensee shall maintain the record of a transfer for a period of one year after the event is included in a report to the Commission.

43 FR 6915

§ 32.26 Gas and aerosol detectors containing byproduct material: requirements for license to manufacture, process, produce, or initially transfer.

An application for a specific license to manufacture, process, or produce gas and aerosol detectors containing byproduct material and designed to protect life or property from fires and airborne hazards, or to initially transfer such products for use pursuant to § 30.20 of this chapter or equivalent regulations of an Agreement State, will be approved if:

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[1] It is the intent of this paragraph that as the magnitude of the potential dose increases above that permitted under normal conditions, the probability that any individual will receive such a dose must decrease. The probabilities have been expressed in general terms to emphasize the approximate nature of the estimates which are to be made. The following values may be used as guides in estimating compliance with the criteria:

Low—not more than one such failure per year for each 10,000 exempt units distributed.

Negligible—not more than one such failure per year for each 1 million exempt units distributed.

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter: *Provided, however,* That the requirements of § 30.33(a) (2) and (3) do not apply to an application for a license to transfer byproduct material in gas and aerosol detectors manufactured, processed or produced pursuant to a license issued by an Agreement State.

(b) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, and conditions of handling, storage, use, and disposal of the gas and aerosol detector to demonstrate that the product will meet the safety criteria set forth in § 32.27. The information should include:

(1) A description of the product and its intended use or uses;

(2) The type and quantity of byproduct material in each unit;

(3) Chemical and physical form of the byproduct material in the product and changes in chemical and physical form that may occur during the useful life of the product;

(4) Solubility in water and body fluids of the forms of the byproduct material identified in paragraphs (b) (3) and (12) of this section;

(5) Details of construction and design of the product as related to containment and shielding of the byproduct material and other safety features under normal and severe conditions of handling, storage, use, and disposal of the product;

(6) Maximum external radiation levels at 5 and 25 centimeters from any external surface of the product, averaged over an area not to exceed 10 square centimeters, and the method of measurement;

(7) Degree of access of human beings to the product during normal handling and use;

(8) Total quantity of byproduct material expected to be distributed in the product annually;

(9) The expected useful life of the product;

34 FR 6653

(10) The proposed methods of labeling or marking the detector and its point—of—sale package to satisfy the requirements of § 32.29(b);

45 FR 38342

(11) Procedures for prototype testing of the product to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, and disposal of the product;

(12) Results of the prototype testing of the product, including any change in the form of the byproduct material contained in the product, the extent to which the byproduct material may be released to the environment, any increase in external radiation levels, and any other changes in safety features;

(13) The estimated external radiation doses and dose commitments relevant to the safety criteria in § 32.27 and the basis for such estimates;

(14) A determination that the probabilities with respect to the doses referred to in § 32.27(c) meet the criteria of that paragraph;

(15) Quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet; and

(16) Any additional information, including experimental studies and tests, required by the Commission.

34 FR 6653

§ 32.27 Same: safety criteria.

An applicant for a license under § 32.26 shall demonstrate that the product is designed and will be manufactured so that:

(a) In normal use and disposal of a single exempt unit, and in normal handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, it is unlikely that the external radiation dose in any one year, or the dose commitment resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the product will exceed the dose to the appropriate organ as specified in Column I of the table in § 32.28.

(b) It is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the product from wear and abuse likely to occur in normal handling and use of the product during its useful life.

(c) In use and disposal of a single exempt unit and in handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, the probability is low that the containment, shielding, or other safety features of the product would fail under such circumstances that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column II of the table in § 32.28, and the probability is negligible that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column III of the table in § 32.28.[1]

§ 32.28 Same: table of organ doses.

Part of body	Column I (rem)	Column II (rem)	Column III (rem)
Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	0.005	0.5	15
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	0.075	7.5	200
Other organs	0.015	1.5	50

34 FR 6653

§ 32.29 Conditions of licenses issued under § 32.26: quality control, labeling, and reports of transfer.

Each person licensed under § 32.26 shall:

(a) Carry out adequate control procedures in the manufacture of the product to assure that each production lot meets the quality control standards approved by the Commission;

43 FR 6915

(b) Label or mark each detector and its point-of-sale package so that:

(1) Each detector has a durable, legible, readily visible label or marking on the external surface of the detector containing:

(i) The following statement: "CONTAINS RADIOACTIVE MATERIAL";

(ii) The name of the radionuclide and quantity of activity; and

(iii) An identification of the person licensed under § 32.26 to transfer the detector for use pursuant to § 30.20 of this chapter or equivalent regulations of an Agreement State.

(2) The labeling or marking specified in paragraph (b)(1) of this section is located where its will be readily visible when the detector is removed from its mounting.

45 FR 38340

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[1] It is the intent of this paragraph that as the magnitude of the potential dose increases above that permitted under normal conditions, the probability that any individual will receive such a dose must decrease. The probabilities have been expressed in general terms to emphasize the approximate nature of the estimates which are to be made. The following values may be used as guides in estimating compliance with the criteria:

Low—not more than one such failure per year for each 10,000 exempt units distributed.

Negligible—not more than one such failure per year for each one million exempt units distributed.

(3) The external surface of the point-of-sale package has a legible, readily visible label or marking containing:

(i) The name of the radionuclide and quantity of activity;

(ii) An identification of the person licensed under § 32.26 to transfer the detector for use pursuant to § 30.20 of this chapter or equivalent regulations of an Agreement State; and

(iii) The following or a substantially similar statement: "THIS DETECTOR CONTAINS RADIOACTIVE MATERIAL AND HAS BEEN MANUFACTURED IN COMPLIANCE WITH U.S. NRC SAFETY CRITERIA IN 10 CFR 32.27. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS."

(4) Each detector and point-of-sale package is provided with such other information as may be required by the Commission; and

45 FR 38340

(c) Maintain records and file a report with the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, with copies to the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter.

(1) The report must include the following information on products transfered to other persons for use under § 30.20 of this chapter or equivalent regulations of an Agreement State—

(i) A description or identification of the type of each product;

(ii) For each radionuclide in each type of product, the total quantity of the radionuclide; and

(iii) The number of units of each type of product transferred during the reporting period.

(2) The licensee shall file the report within 30 days following—

(i) Five years after filing the preceding report; or

(ii) Filing an application for renewal of the license under § 30.37; or

(iii) Notifying the Commission under § 30.34(f) of the licensee's decision to permanently discontinue activities authorized pursuant to the license issued under § 32.26.

(3) The report must cover the period between the filing of the preceding report and the occurrences specified in paragraphs (c)(2) (i), (ii), or (iii) of this section. If no transfers of byproduct material have been made under § 32.26 during the reporting period, the report must so indicate.

(4) The licensee shall maintain the record of a transfer for a period of one year after the event is included in a report to the Commission.

48 FR 12331

§ 32.40 Schedule A—Prototype tests for automobile lock illuminators.

An applicant for a license pursuant to § 32.14 to install lock illuminators into automobile locks, or to initially transfer lock illuminators in automobile locks for use pursuant to § 30.15 of this chapter shall conduct the following prototype tests on each of five prototype devices, consisting of the automobile lock with the installed illuminator in the following order:

43 FR 6915

(a) The device shall be subjected to 100 hours of accelerated weathering in a suitable weathering machine which simulates the most severe conditions of normal use;

(b) The device shall be dropped upon a concrete or iron surface in a 3-foot free gravitational fall, or shall be subjected to an equivalent treatment in a test device simulating such a fall. The drop test shall be repeated 100 times from random orientations;

(c) The device shall be attached to a vibratory fixture and vibrated at a rate of not less than 26 cycles per second and a vibration acceleration of not less than 2 G for a period of not less than 1 hour;

(d) On completion of the foregoing tests, the device shall be immersed in 30 inches of water for 24 hours and shall show no visible evidence of water entry into the lock illuminator. Absolute pressure of the air above the water shall then be reduced to 1 inch of mercury. Lowered pressure shall be maintained for 1 minute or until air bubbles cease to be given off by the water, whichever is the longer. Pressure shall then be increased to normal atmospheric pressure. Any evidence of bubbles emanating from within the lock illuminator, or water entering the lock illuminator, shall be considered leakage;

(e) After each of the tests prescribed by this section, each device shall be examined for evidence of physical damage and for loss of tritium or promethium-147. Any evidence of damage to or failure of any device which could affect the containment of the tritium or promethium-147 in such devices shall be cause for rejection of the design on which such prototype devices were constructed or manufactured if the damage or failure is attributable to design defect. Loss of tritium or promethium-147 from each tested device shall be measured both by sampling the immersion test water used in paragraph (d) of this section and by wiping with filter paper the entire accessible area of the lock illuminator. Measurements of tritium or promethium-147 shall be made in an apparatus calibrated to measure tritium or promethium-147, as appropriate. If more than 0.1 percent of the original amount of tritium or promethium-147 in the device is found in the immersion test water of the test in paragraph (d) of this section, or if more than 2,200 disintegrations per minute of tritium or promethium-147 on the filter paper is measured after any of the tests in paragraphs (a) to (d) of this section the device shall be rejected.

30 FR 8185

Subpart B—Generally Licensed Items

§ 32.51 Byproduct material contained in devices for use under § 31.5; requirements for license to manufacture, or initially transfer.

(a) An application for a specific license to manufacture, or initially transfer devices containing byproduct material to persons generally licensed under § 31.5 of this chapter or equivalent regulations of an Agreement State will be approved if:

43 FR 6915

(1) The applicant satisfies the general requirements of § 30.33 of this chapter;

(2) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

(i) The device can be safely operated by persons not having training in radiological protection;

(ii) Under ordinary conditions of handling, storage and use of the device, the byproduct material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of one calendar quarter a dose in excess of 10 percent of the limits specified in the table in § 20.101(a) of this chapter; and

(iii) Under accident conditions (such as fire and explosion) associated with handling, storage and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column IV of the table in § 32.24.

(3) Each device bears a durable, legible, clearly visible label or labels approved by the Commission which contain in a clearly identified and separate statement:

(i) Instructions and precautions necessary to assure safe installation, operation, and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information);

39 FR 43531

39 FR 43531

(ii) The requirements, or lack of requirement, for leak testing, or for testing any on-off mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity; and

(iii) The information called for in the following statement in the same or substantially similar form: [1]

43 FR 5915

> **The receipt, possession, use, and transfer of this device Model ———[2] Serial No. ———[2], are subject to a general license or the equivalent and the regulations of the U.S. NRC or of a State with which the NRC has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.**
>
> **CAUTION—RADIOACTIVE MATERIAL**
>
> **(Name of manufacturer, or initial transferor)[2]————————**

(b) In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or for both, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices, and by design features which have a significiant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the Commission will consider information which includes, but is not limited to:

(1) Primary containment (source capsule);

(2) Protection of primary containment;

(3) Method of sealing containment,

(4) Containment construction materials;

(5) Form of contained radioactive material;

(6) Maximum temperature withstood during prototype tests;

(7) Maximum pressure withstood during prototype tests;

(8) Maximum quantity of contained radioactive material;

(9) Radiotoxicity of contained radioactive material; and

(10) Operating experience with identical devices or similarly designed and constructed devices.

39 FR 43537

(c) In the event the applicant desires that the general licensee under § 31.5 of this chapter, or under equivalent regulations of an Agreement State, be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, he shall include in his application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities and the bases for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a calendar quarter dose in excess of 10 percent of the limits specified in the table in § 20.101(a) of this chapter.

§ 32.51a Same: conditions of licenses.

Each person licensed under § 32.51 shall:

(a) Furnish a copy of the general license contained in § 31.5 of this chapter to each person to whom he directly or through an intermediate person transfers byproduct material in a device for use pursuant to the general license contained in § 31.5 of this chapter.

39 FR 43531

(b) Furnish a copy of the general license contained in the Agreement State's regulation equivalent to § 31.5 of this chapter, or alternatively, furnish a copy of the general license contained in § 31.5 of this chapter, to each person to whom he directly or through an intermediate person transfers byproduct material in a device for use pursuant to the general license of an Agreement State. If a copy of the general license in § 31.5 of this chapter is furnished to such person, it shall be accompanied by a note explaining that use of the device is regulated by the Agreement State under requirements substantially the same as those in § 31.5 of this chapter.

§ 32.52 Same: material transfer reports and records.

43 FR 6915

Each person licensed under § 32.51 to initially transfer devices to generally licensed persons shall:

(a) Report to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, with a copy to the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter, all transfers of such devices to persons for use under the general license in § 31.5 of this chapter. Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Commission and the general licensee, the type and model number of device transferred, and the quantity and type of byproduct material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship

41 FR 16445

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[1] Devices licensed under § 32.51 prior to January 19, 1975 may bear labels authorized by the regulations in effect on January 1, 1975.

[2] The model, serial number, and the name of the manufacturer, or initial transferor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.

to the intended user. If no transfers have been made to persons generally licensed under § 31.5 of this chapter during the reporting period, the report shall so indicate. The report shall cover each calendar quarter and shall be filed within 30 days thereafter. The first report to be filed pursuant to this paragraph as revised and effective on January 15, 1975, shall cover the first calendar quarter in 1975. The report, if any, required for the fourth calendar quarter in 1974 shall be filed pursuant to the requirements of this paragraph in effect on January 14, 1975.

41 FR 16445

(b) Report to the responsible Agreement State agency all transfers of such devices to persons for use under a general license in an Agreement State's regulation equivalent to § 31.5 of this chapter. Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency and the general licensee, the type and model number of device transferred, and the quantity and type of byproduct material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. The report shall be submitted within 30 days after the end of each calendar quarter in which such a device is transferred to the generally licensed person. If no transfers have been made to a particular Agreement State during the reporting period, this information shall be reported to the responsible Agreement State agency upon request of the agency. The first report, if any, to be filed pursuant to this paragraph as revised and effective on January 15, 1975, shall cover the first calendar quarter in 1975.

(c) Keep records showing the name, address, and a point of contact for each general licensee to whom he directly or through an intermediate person transfers byproduct material in devices for use pursuant to the general license provided in § 31.5 of this chapter or equivalent regulations of an Agreement State. The records shall show the date of each transfer, the isotope and quantity of radioactivity in each device transferred, the identity of any intermediate person, and compliance with the report requirements of this section.

39 FR 43531

The records required by this paragraph shall be maintained for a period of five years from the date of the recorded event.

41 FR 18300

§ 32.53 Luminous safety devices for use in aircraft: requirements for license to manufacture, assemble, repair or initially transfer.

An application for a specific license to manufacture, assemble, repair or initially transfer luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under § 31.7 of this chapter, will be approved if:

43 FR 6915

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter;

(b) The applicant submits sufficient information regarding each device pertinent to evaluation of the potential radiation exposure, including:

(1) Chemical and physical form and maximum quantity of tritium or promethium-147 in each device;

(2) Details of construction and design;

(3) Details of the method of binding or containing the tritium or promethium-147;

(4) Procedures for and results of prototype testing to demonstrate that the trititum or promethium-147 will not be released to the environment under the most severe conditions likely to be encountered in normal use;

(5) Any quality control procedures proposed as alternatives to those prescribed by § 32.55;

(6) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the device.

30 FR 8185

(c) Each device will contain no more than 10 curies of tritium or 300 millicuries of promethium-147. The levels of radiation from each device containing promethium-147 will not exceed 0.5 millirad per hour at 10 centimeters from any surface when measured through 50 milligrams per square centimeter of absorber.

33 FR 6462

(d) The Commission determines that:

(1) The method of incorporation and binding of the tritium or promethium-147 in the device is such that the tritium or promethium-147 will not be released under the most severe conditions which are likely to be encountered in normal use and handling of the device;

(2) The tritium or promethium-147 is incorporated or enclosed so as to preclude direct physical contact by any person with it;

(3) The device is so designed that it cannot easily be disassembled; and

(4) The device has been subjected to and has satisfactorily passed the prototype tests prescribed by § 32.101, Schedule B.

30 FR 8185

§ 32.54 Same: labeling of devices.

(a) A person licensed under § 32.53 to manufacture, assemble, or initially transfer devices containing tritium or promethium-147 for distribution to persons generally licensed under § 31.7 of this chapter shall, except as provided in paragraph (b) of this section, affix to each device a label containing the radiation symbol prescribed by § 20.203(a) of this chapter, such other information as may be required by the Commission including disposal instructions when appropriate, and the following or a substantially similar statement which contains the information called for in the following statement:[1]

> The receipt, possession, use, and transfer of this device, Model*__________, Serial No.*_____, containing ______________
> (Identity and quantity
> ______________ are subject to a gen-
> of radioactive material)
> eral license or the equivalent and the regulations of the U.S. NRC or of a State with which the NRC has entered into an agreement for the exercise of regulatory authority. Do not remove this label.
>
> CAUTION–RADIOACTIVE MATERIAL
>
> ______________________________
>
> (Name of manufacturer, assembler, or initial transferor)*

43 FR 6915

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[1] Devices licensed under section 32.53 prior to January 19, 1975, may bear labels authorized by the regulations in effect on January 1, 1975.

*The model, serial number, and name of manufacturer, assembler, or initial transferor† may be omitted from this label provided they are elsewhere specified in labeling affixed to the device.

(b) If the Commission determines that it is not feasible to affix a label to the device containing all the information called for in paragraph (a) of this section, it may waive the requirements of that paragraph and require in lieu thereof that:

(1) A label be affixed to the device identifying:

(i) The manufacturer, assembler, or initial transferor;‡ and

(ii) The type of radioactive material; and

43 FR 6915

(2) A leaflet bearing the following information be enclosed in or accompany the container in which the device is shipped:

(i) The name of the manufacturer, assembler, or initial transferor,

(ii) The type and quantity of radioactive material,

(iii) The model number,

(iv) A statement that the receipt, possession, use, and transfer of the device are subject to a general license or the equivalent and the regulations of the U.S. NRC or of an Agreement State, and

(v) Such other information as may be required by the Commission, including disposal instructions when appropriate.

33 FR 16330

§ 32.55 Same: quality assurance; prohibition of transfer.

(a) Each person licensed under § 32.53 shall visually inspect each device and shall reject any which has an observable physical defect that could affect containment of the tritium or promethium-147.

30 FR 8185

(b) Each person licensed under § 32.53 shall take a random sample of the size required by the table in § 32.110 for Lot Tolerance Percent Defective of 5.0 percent from each inspection lot, and shall subject each unit in the sample to the following tests:

(1) Each device shall be immersed in 30 inches of water for 24 hours and shall show no visible evidence of water entry. Absolute pressure of the air above the water shall then be reduced to 1 inch of mercury. Lowered pressure shall be maintained for 1 minute or until air bubbles cease to be given off by the water, whichever is the longer. Pressure shall then be increased to normal atmospheric pressure. Any device which leaks as evidenced by bubbles emanating from within the device, or water entering the device, shall be considered as a defective unit.

(2) The immersion test water from the preceding test in paragraph (b) (1) of this section shall be measured for tritium or promethium-147 content by an apparatus that has been calibrated to measure tritium or promethium-147, as appropriate. If more than 0.1 percent of the original amount of tritium or promethium-147 in any device is found to have leaked into the immersion test water, the leaking device shall be considered as a defective unit.

(3) The levels of radiation from each device containing promethium-147 shall be measured. Any device which has a radiation level in excess of 0.5 millirad per hour at 10 centimeters from any surface when measured through 50 milligrams per square centimeter of absorber, shall be considered as a defective unit.

(c) An application for a license or for amendment of a license may include a description of procedures proposed as alternatives to those prescribed by paragraph (b) of this section, and proposed criteria for acceptance under those procedures. The Commission will approve the proposed alternative procedures if the applicant demonstrates that:

(1) They will consider defective any sampled device which has a leakage rate exceeding 0.1 percent of the original quantity of tritium or promethium-147 in any 24-hour period; and

(2) The operating characteristic curve or confidence interval estimate for the alternative procedures provides a Lot Tolerance Percent Defective of 5.0 percent at the consumer's risk of 0.10.

(d) No person licensed under § 32.53 shall transfer to persons generally licensed under § 31.7 of this chapter:

(1) Any luminous safety device which has been tested and found defective under the criteria and procedures specified in this section, unless the defective units have been repaired or reworked and have then met the tests set out in paragraph (b) of this section; or

(2) Any inspection lot which has been rejected as a result of the procedures in § 32.110 or alternative procedures in paragraph (c) of this section, unless the defective units have been sorted and removed or have been repaired or reworked and have then met the tests set out in paragraph (b) of this section.

39 FR 22129

§ 32.56 Same: material transfer reports.

Each person licensed under § 32.53 shall file an annual report with the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, with a copy to the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter, which shall state the total quantity of tritium or promethium-147 transferred to persons generally licensed under § 31.7 of this chapter. The report shall identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium or promethium-147 in each kind of device. Each report shall cover the year ending June 30 and shall be filed within thirty (30) days thereafter.

41 FR 16445

§ 32.57 Calibration or reference sources containing americium-241: requirements for license to manufacture or initially transfer.

An application for a specific license to manufacture or initially transfer calibration or reference sources containing americium-241, for distribution to persons generally licensed under § 31.8 of this chapter, will be approved if:

43 FR 6915

(a) The applicant satisfies the general requirements of § 30.33 of this chapter;

(b) The applicant submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:

(1) Chemical and physical form and maximum quantity of americium-241 in the source;

(2) Details of construction and design;

(3) Details of the method of incorporation and binding of the americium-241 in the source;

(4) Procedures for and results of prototype testing of sources, which are designed to contain more than 0.005 microcurie of americium-241, to demonstrate that the americium-241 contained in each source will not be released or be removed from the source under normal conditions of use;

(5) Details of quality control procedures to be followed in manufacture of the source;

(6) Description of labeling to be affixed to the source or the storage container for the source;

(7) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the source.

(c) Each source will contain no more than 5 microcuries of americium-241.

(d) The Commission determines, with respect to any type of source containing more than 0.005 microcurie of americium-241, that:

(1) The method of incorporation and binding of the americium-241 in the source is such that the americium-241 will not be released or be removed from the source under normal conditions of use and handling of the source; and

(2) The source has been subjected to and has satisfactorily passed the prototype tests prescribed by § 32.102, Schedule C.

30 FR 8185

§ 32.58 Same: labeling of devices.

Each person licensed under § 32.57 shall affix to each source, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement which contains the information called for in the following statement:*

The receipt, possession, use and transfer of this source, Model ______, Serial No. ______, are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION – RADIOACTIVE MATERIAL – THIS SOURCE CONTAINS AMERICIUM-241. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

(Name of manufacturer or initial transferor)

43 FR 6915

§ 32.59 Same: leak testing of each source.

Each person licensed under § 32.57 shall perform a dry wipe test upon each source containing more than 0.1 microcurie of americium-241 prior to transferring the source to a general licensee under § 31.8 of this chapter. This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the paper shall be measured by using radiation detection instrumentation capable of detecting 0.005 microcurie of americium-241. If any such test discloses more than 0.005 microcurie of radioactive material, the source shall be deemed to be leaking or losing americium-241 and shall not be transferred to a general licensee under § 31.8 of this chapter.

30 FR 8185

§ 32.60 [Revoked 42 FR 43965.]

§ 32.61 Ice detection devices containing strontium-90: requirements for license to manufacture or initially transfer.

An application for a specific license to manufacture or initially transfer ice detection devices containing strontium-90 for distribution to persons generally licensed under § 31.10 of this chapter will be approved if:

43 FR 6915

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter;

(b) The applicant submits sufficient information regarding each type of device pertinent to evaluation of the potential radiation exposure, including:

(1) Chemical and physical form and maximum quantity of strontium-90 in the device;

(2) Details of construction and design of the source of radiation and its shielding;

(3) Radiation profile of a prototype device;

(4) Procedures for and results of prototype testing of devices to demonstrate that the strontium-90 contained in each device will not be released or be removed from the device under the most severe conditions likely to be encountered in normal handling and use;

(5) Details of quality control procedures to be followed in manufacture of the device;

(6) Description of labeling to be affixed to the device;

(7) Instructions for handling and installation of the device;

(8) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the device.

(c) Each device will contain no more than 50 microcuries of strontium-90 in an insoluble form.

(d) Each device will bear durable, legible labeling which includes the radiation caution symbol prescribed by § 20.203(a) of this chapter, a statement that the device contains strontium-90 and the quantity thereof, instructions for disposal and statements that the device may be possessed pursuant to a general license, that the manufacturer or civil authorities should be notified if the device is found, that removal of the labeling is prohibited and that disassembly and repair of the device may be performed only by a person holding a specific license to manufacture or service such devices.

(e) The Commission determines that:

(1) The method of incorporation and binding of the strontium-90 in the device is such that the strontium-90 will not be released from the device under the most severe conditions which are likely to be encountered in normal use and handling of the device;

(2) The strontium-90 is incorporated or enclosed so as to preclude direct physical contact by any individual with it and is shielded so that no individual will receive a radiation exposure to a major portion of his body in excess of 0.5 rem in a year under ordinary circumstances of use;

(3) The device is so designed that it cannot be easily disassembled;

(4) The device has been subjected to and has satisfactorily passed the prototype tests prescribed by § 32.103; and

(5) Quality control procedures have been established to satisfy the requirements of § 32.62.

30 FR 9904

§ 32.62 Same: quality assurance; prohibition of transfer.

[Introductory sentence deleted 43 FR 6915.]

39 FR 22129

(a) Each person licensed under § 32.61 shall visually inspect each device and shall reject any which has an observable physical defect that could affect containment of the strontium-90.

(b) Each person licensed under § 32.61 shall test each device for possible

30 FR 9904

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*Sources licensed under section 32.57 prior to January 19, 1975, may bear labels authorized by the regulations in effect on January 1, 1975.

loss of strontium-90 or for contamination by wiping with filter paper an area of at least 100 square centimeters on the outside surface of the device, or by wiping the entire surface area if it is less than 100 square centimeters. The detection on the filter paper of more than 2,200 disintegrations per minute of radioactive material per 100 square centimeters of surface wiped shall be cause for rejection of the tested device.

(c) Each person licensed under § 32.61 shall take a random sample of the size required by the table in § 32.110 for Lot Tolerance Percent Defective of 5.0 percent from each inspection lot, and shall subject each unit in the sample to the following tests:

(1) Each device shall be immersed in 30 inches of water for 24 hours and shall show no visible evidence of physical contact between the water and the strontium-90. Absolute pressure of the air above the water shall then be reduced to 1 inch of mercury. Lowered pressure shall be maintained for 1 minute or until air bubbles cease to be given off by the water, whichever is the longer. Pressure shall then be increased to normal atmospheric pressure. Any device which leaks, as evidenced by physical contact between the water and the strontium-90, shall be considered as a defective unit.

(2) The immersion test water from the preceding test in paragraph (c)(1) of this section shall be measured for radioactive material. If the amount of radioactive material in the immersion test water is greater than 0.1 percent of the original amount of stronium-90 in any device, the device shall be considered as a defective unit.

(d) An application for a license or for amendment of a license may include a description of procedures proposed as alternatives to those prescribed by paragraph (c) of this section, and proposed criteria for acceptance under those procedures. The Commission will approve the proposed alternative procedures if the applicant demonstrates that:

(1) They will consider defective any sampled device which has a leakage rate exceeding 0.1 percent of the original quantity of strontium-90 in any 24-hour period; and

(2) The operating characteristic curve or confidence interval estimate for the alternative procedures provides a Lot Tolerance Percent Defective of 5.0 percent at the consumer's risk of 0.10.

(e) No person licensed under § 32.61 shall transfer to persons generally licensed under § 31.10 of this chapter:

(1) Any device which has been tested and found defective under the criteria and procedures specified in this § 32.62 unless the defective units have been repaired or reworked and then met the tests set out in paragraph (c) of this section; or

(2) Any inspection lot which has beeen rejected as a result of the procedures in § 32.110 or alternative procedures in paragraph (d) of this section, unless the defective units have been sorted and removed or have been repaired or reworked and have then met the tests set out in paragraph (c) of this section.

§ 32.63 [Revoked 42 FR 43965.]

§ 32.70 Manufacture and distribution of byproduct materials for medical use under general license.

An application for a specific license to distribute byproduct material for use by physicians under the general license of § 35.31 of this chapter will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter;

(b) The applicant submits evidence that the byproduct material is to be manufactured, labeled, and packaged in accordance with a new drug application which the Commissioner of Food and Drugs, Food and Drug Administration, has approved, or in accordance with a license for a biologic product issued by the Secretary, Department of Health, Education, and Welfare;

(c) The following statement, or a substantially similar statement which contains the information called for in the following statement, appears on the label affixed to the container or appears in the leaflet or brochure which accompanies the package: *

> This radioactive drug may be received, possessed and used only by physicians licensed to dispense drugs in the practice of medicine. Its receipt, possession, use and transfer are subject to the regulations and a general license of the United States Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.
>
> _______________
>
> (Name of manufacturer)

§ 32.71 Manufacture and distribution of byproduct material for certain in vitro clinical or laboratory testing under general license.

An application for a specific license to manufacture or distribute byproduct material for use under the general license of § 31.11 of this chapter will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter.

(b) The byproduct material is to be prepared for distribution in prepackaged units of:

(1) Iodine-125 in units not exceeding 10 microcuries each.

(2) Iodine-131 in units not exceeding 10 microcuries each.

(3) Carbon-14 in units not exceeding 10 microcuries each.

(4) Hydrogen-3 (tritium) in units not exceeding 50 microcuries each.

(5) Iron-59 in units not exceeding 20 microcuries each.

(6) Selenium-75 in units not exceeding 10 microcuries each.

(7) Mock Iodine-125 in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each.

(c) Each prepackaged unit bears a durable, clearly visible label:

(1) Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 microcuries of iodine-131, iodine-125, selenium-75, or carbon-14; 50 microcuries of hydrogen-3 (tritium); 20 microcuries of iron-59; or Mock Iodine-125 in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each; and

(2) Displaying the radiation caution symbol described in § 20.203(a)(1) of this chapter and the words, "Caution, Radioactive Material", and "Not for Internal or External Use in Humans or Animals."

(d) The following statement, or a substantially similar statement which con-

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*Radioactive drugs licensed under § 32.70 prior to January 19, 1975, may bear labels authorized by the regulations in effect on January 1, 1975.

33 FR 16553 tains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

44 FR 50324

> This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.
>
> ______________________________
>
> (Name of Manufacturer)

42 FR 26986 (e) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such byproduct material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in § 20.301 of Part 20 of this chapter.

39 FR 26143

§ 32.72 Manufacture and distribution of radiopharmaceuticals containing byproduct material for medical use under group licenses.

(a) An application for a specific license to manufacture and distribute radiopharmaceuticals containing byproduct material for use by persons licensed pursuant to § 35.14 of this chapter for the uses listed in Group I, Group II, Group IV, or Group V of Schedule A, § 35.100 of this chapter will be approved if:

(1) The applicant satisfies the general requirements specified in § 30.33 of this chapter;

(2) The applicant submits evidence that:

(i) The radiopharmaceutical containing byproduct material will be manufactured, labeled, and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), a biologic product license issued by FDA, or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) accepted by FDA; or

(ii) The manufacture and distribution of the radiopharmaceutical containing byproduct material is not subject to the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act.

(3) The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the byproduct material that is appropriate for safe handling and storage of radiopharmaceuticals by group licensees; and

(4) (i) The label affixed to each package of the radiopharmaceutical contains information on the radionuclide, quantity, and date of assay, and the label affixed to each package, or the leaflet or brochure which accompanies each package, contains a statement that the radiopharmaceutical is licensed by the U.S. Nuclear Regulatory Commission for distribution to persons licensed pursuant to § 35.14 and § 35.100 Group I, Group II, Group IV, or Group V of 10 CFR Part 35, as appropriate, or under equivalent licenses of Agreement States or that an application for such license has been filed with the Atomic Energy Commission on or before October 15, 1974, and is still pending. 39 FR 26143

(ii) The labels, leaflets or brochures required by this paragraph are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

(b) If an application is filed pursuant to paragraph (a) of this section on or before October 15, 1974, for a license to manufacture and distribute a radiopharmaceutical that was distributed commercially on or before August 16, 1974, the applicant may continue the distribution of such radiopharmaceutical to group licensees until the Commission issues the license or notifies the applicant otherwise.

§ 32.73 Manufacture and distribution of generators or reagent kits for preparation of radiopharmaceuticals containing byproduct material.

(a) An application for a specific license to manufacture and distribute generators or reagent kits containing byproduct material for preparation of radiopharmaceuticals by persons licensed pursuant to § 35.14 of this chapter for the uses listed in Group III of Schedule A, § 35.100 of this chapter will be approved if (See Note 1):

(1) The applicant satisfies the general requirements specified in § 30.33 of this chapter;

(2) The applicant submits evidence that:

(i) The generator or reagent kit is to be manufactured, labeled, and packaged in accordance with the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), a biologic product license issued by FDA, or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) accepted by FDA; or

(ii) The manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act.

39 FR 26143 (3) The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the byproduct material contained in the generator or reagent kit;

(4) The label affixed to the generator or reagent kit contains information on the radionuclide, quantity, and date of assay; and

(5) The label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator or reagent kit, contains:

(i) Adequate information, from a radiation safety standpoint, on the procedures to be followed and the equipment and shielding to be used in eluting the generator or processing radioactive material with the reagent kit, and

(ii) A statement that this generator or reagent kit (as appropriate) is approved for use by persons licensed by the U.S. Nuclear Regulatory Commission pursuant to §§ 35.14 and 35.100 Group III of 10 CFR Part 35 or under equivalent licenses of Agreement States, or that an application for such license has been filed with the Atomic Energy Commission on or before October 15, 1974, and is still pending.

The labels, leaflets or brochures required by this paragraph are in addition to the labeling required by FDA and they may be separate from or, with the approval of FDA, may be combined with the labeling

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[1] Labels authorized by the regulations in effect on September 26, 1979, may be used until one year from September 27, 1979.

required by FDA.

(b) If an application is filed pursuant to paragraph (a) of this section on or before October 15, 1974, for a license to manufacture and distribute a generator or reagent kit that was distributed commercially on or before August 16, 1974, the applicant may continue the distribution of such generator or reagent kit until the Commission issues the license or notifies the applicant otherwise.

NOTE 1. Although the Commission does not regulate the manufacture and distribution of reagent kits that do not contain byproduct material, it does regulate the use of such reagent kits for the preparation of radiopharmaceuticals containing byproduct material as part of its licensing and regulation of the users of byproduct material. Any manufacturer of reagent kits that do not contain byproduct material who desires to have his reagent kits approved by the Commission for use by persons licensed pursuant to § 35.14 and Group III of Schedule A, § 35.100 of this chapter may submit the pertinent information specified in this § 32.73.

§ 32.74 Manufacture and distribution of sources or devices containing byproduct material for medical use.

(a) An application for a specific license to manufacture and distribute sources and devices containing byproduct material to persons licensed pursuant to § 35.14 of this chapter for use as a calibration or reference source or for the uses listed in Group VI Schedule A, § 35.100 of this chapter will be approved if:

39 FR 26143

(1) The applicant satisfies the general requirements in § 30.33 of this chapter;

(2) The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

(i) The byproduct material contained, its chemical and physical form, and amount:

(ii) Details of design and construction of the source or device;

(iii) Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents;

(iv) For devices containing byproduct material, the radiation profile of a prototype device;

(v) Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests;

(vi) Procedures and standards for calibrating sources and devices;

(vii) Legend and methods for labeling sources and devices as to their radioactive content;

(viii) Instructions for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; *Provided*, That instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label;

(3) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the (name of source or device) is licensed by the U.S. Nuclear Regulatory Commission for distribution to persons licensed pursuant to §§ 35.14 and 35.100 Group VI of 10 CFR Part 35 or under equivalent licenses of Agreement States or that a pending application for such license has been filed with the Atomic Energy Commission on or before October 15, 1974; *Provided*, That such labeling for sources which do not require long term storage (e.g., gold 198 seeds) may be on a leaflet or brochure which accompanies the sources.

39 FR 26143

(b) (1) In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a signficiant bearing on the probability or consequences of leakage of radioactive material from the source.

(2) In determining the acceptable interval for test of leakage of radioactive material, the Commission will consider information that includes, but is not limited to:

(i) Primary containment (source capsule);

(ii) Protection of primary containment;

(iii) Method of sealing containment;

(iv) Containment construction materials;

(v) Form of contained radioactive material;

(vi) Maximum temperature withstood during prototype tests;

(vii) Maximum pressure withstood during prototype tests;

(viii) Maximum quantity of contained radioactive material;

(ix) Radiotoxicity of contained radioactive material;

(x) Operating experience with identical sources or devices or similarly designed and constructed sources or devices.

(c) If an application is filed pursuant to paragraph (a) of this section on or before October 15, 1974, for a license to manufacture and distribute a source or device that was distributed commercially on or before August 16, 1974, the applicant may continue the distribution of such source or device to group licensees until the Commission issues the license or notifies the applicant otherwise.

39 FR 26143

§ 32.101 Schedule B—Prototype tests for luminous safety devices for use in aircraft.

An applicant for a license pursuant to § 32.53 shall conduct prototype tests on each of five prototype luminous safety devices for use in aircraft as follows:

(a) *Temperature-altitude test*. The device shall be placed in a test chamber as it would be used in service. A temperature-altitude condition schedule shall be followed as outlined in the following steps:

Step 1. The internal temperature of the test chamber shall be reduced to -62° C. (-80° F.) and the device shall be maintained for at least 1 hour at this temperature at atmospheric pressure.

Step 2. The internal temperature of the test chamber shall be raised to -54° C. (-65° F.) and maintained until the temperature of the device has stabilized at -54° C. at atmospheric pressure.

Step 3. The atmospheric pressure of the chamber shall be reduced to 83 millimeters of mercury absolute pressure while the chamber temperature is maintained at -54° C.

Step 4. The internal temperature of the chamber shall be raised to -10° C. (+14° F.) and maintained until the temperature of the device has stabilized at -10° C., and the internal pressure of the chamber shall then be adjusted to atmospheric pressure. The test chamber door shall then be opened in order that frost will form on the device, and shall remain open until the frost has melted but not long enough to allow the moisture to evaporate. The door shall then be closed.

30 FR 8185

Step 5. The internal temperature of the chamber shall be raised to +85° C. (185° F.) at atmospheric pressure. The temperature of the device shall be stabilized at +85° C. and maintained for 2 hours. The device shall then be visually inspected to determine the extent of any deterioration.

Step 6. The chamber temperature shall be reduced to +71° C. (160° F.) at atmospheric pressure. The temperature of the device shall be stabilized at +71° C. for a period of 30 minutes.

Step 7. The chamber temperature shall be reduced to +55° C. (130° F.) at atmospheric pressure. The temperature of the device shall be stabilized at this temperature for a period of 4 hours.

Step 8. The internal temperature of the chamber shall be reduced to +30° C. (86° F.) and the pressure to 138 millimeters of mercury absolute pressure and stabilized. The device shall be maintained under these conditions for a period of 4 hours.

30 FR 8185

Step 9. The temperature of the test chamber shall be raised to +35° C. (95° F.) and the pressure reduced to 83 millimeters of mercury absolute pressure and stabilized. The device shall be maintained under these conditions for a period of 30 minutes.

30 FR 8185

Step 10. The internal pressure of the chamber shall be maintained at 83 millimeters of mercury absolute pressure and the temperature reduced to +20° C. (68° F.) and stabilized. The device shall be maintained under these conditions for a period of 4 hours.

(b) *Vibration tests.* This procedure applies to items of equipment (including vibration isolating assemblies) intended to be mounted directly on the structure of aircraft powered by reciprocating, turbojet, or turbo-propeller engines or to be mounted directly on gas-turbine engines. The device shall be mounted on an apparatus dynamically similar to the most severe conditions likely to be encountered in normal use. At the end of the test period, the device shall be inspected thoroughly for possible damage. Vibration tests shall be conducted under both resonant and cycling conditions according to the following Vibration Test Schedule (Table I):

VIBRATION TEST SCHEDULE

TABLE I

[Times shown refer to one axis of vibration]

Type	Vibration at room temperature	Vibration at 160° F. (71° C.)	Vibration at −65° F. (−54° C.)
	Minutes	*Minutes*	*Minutes*
Resonance ———	60	15	15
Cycling ———	60	15	15

(1) *Determination of resonance frequency.* Individual resonance frequency surveys shall be conducted by applying vibration to each device along each of any set of three mutually perpendicular axes and varying the frequency of applied vibration slowly through a range of frequencies from 5 cycles per second to 500 cycles per second with the double amplitude of the vibration not exceeding that shown in Figure 1 for the related frequency.

30 FR 8185

(2) *Resonance tests.* The device shall be vibrated at the determined resonance frequency for each axis of vibration for the periods and temperature conditions shown in Table I and with the applied double amplitude specified in Figure 1 for that resonance frequency. When more than one resonant frequency is encountered with vibration applied along any one axis, the test period may be accomplished at the most severe resonance or the period may be divided

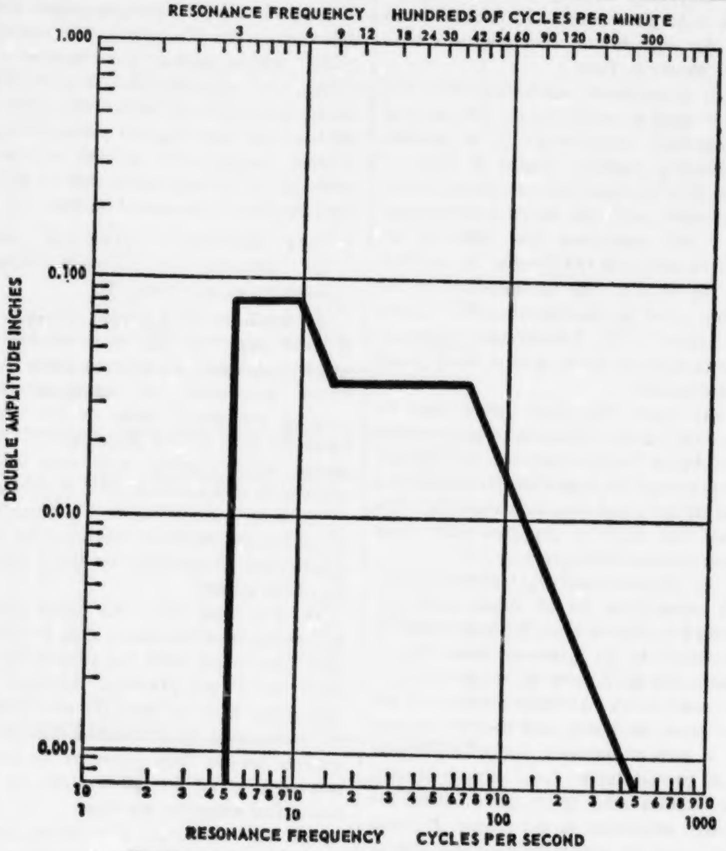

FIGURE 1—Amplitude of vibration at resonance frequency.

among the resonant frequencies, whichever is considered most likely to produce failure. When resonant frequencies are not apparent within the specified frequency range, the specimen shall be vibrated for periods twice as long as those shown for resonance in Table I at a frequency of 55 cycles per second and an applied double amplitude of 0.060 inch.

(3) *Cycling.* Devices to be mounted only on vibration isolators shall be tested by applying vibration along each of three mutually perpendicular axes of the device with an applied double amplitude of 0.060 inch and the frequency cycling between 10 and 55 cycles per second in 1-minute cycles for the periods and temperature conditions shown in Table I. Devices to be installed in aircraft without vibration isolators shall be tested by applying vibration along each of three mutually perpendicular axes of the device with an applied double amplitude of 0.036 inch or an applied acceleration of 10G, whichever is the limiting value, and the frequency cycling between 10 and 500 cycles per second in 15-minute cycles for the periods and temperature conditions shown in Table I.

(c) *Accelerated weathering tests.* The device shall be subjected to 100 hours of accelerated weathering in a suitable weathering machine. Panels of Corex D glass shall surround the arc to cut off the ultraviolet radiation below a wavelength of 2,700 angstroms. The light of the carbon arcs shall fall directly on the face of the device. The temperature at the sample shall be maintained at 50° C. plus or minus 3° C Temperature measurements shall be made with a black panel thermometer.

30 FR 8185

(d) *Shock test.* The device shall be dropped upon a concrete or iron surface in a 3-foot free gravitational fall, or shall be subjected to equivalent treatment in a test device simulating such a free fall. The drop test shall be repeated 100 times from random orientations.

(e) *Hermetic seal and waterproof test.* On completion of all other tests prescribed by this section, the device shall be immersed in 30 inches of water for 24 hours and shall show no visible evidence of water entry. Absolute pressure of the air above the water shall then be reduced to 1 inch of mercury. Lowered pressure shall be maintained for 1 minute or until air bubbles cease to be given off by the water, whichever is the longer. Pressure shall then be increased to normal atmospheric pressure. Any evidence of bubbles emanating from within the device, or water entering the device, shall be considered leakage.

(f) *Observations.* After each of the tests prescribed by this section, each device shall be examined for evidence of physical damage and for loss of tritium or promethium-147. Any evidence of damage to or failure of any device which could affect containment of the tritium or promethium-147 shall be cause for rejection of the design if the damage or failure is attributable to a design defect. Loss of tritium or promethium-147 from each tested device shall be measured by wiping with filter paper an area of at least 100 square centimeters on the outside surface on the device, or by wiping the entire surface area if it is less than 100 square centimeters. The amount of tritium or promethium-147 in the water used in the hermetic seal and waterproof test prescribed by test paragraph (e) of this section shall also be measured. Measurements shall be made in an apparatus calibrated to measure tritium or promethium-147, as appropriate. The detection on the filter paper of more than 2,200 disintegrations per minute of tritium or promethium-147 per 100 square centimeters of surface wiped or in the water of more than 0.1 percent of the original amount of tritium or promethium-147 in any device shall be cause for rejection of the tested device.

30 FR 8185

§ 32.102 Schedule C—Prototype tests for calibration or reference sources containing americium-241.

An applicant for a license pursuant to § 32.57 shall, for any type of source which is designed to contain more than 0.005 microcurie of americium-241, conduct prototype tests, in the order listed, on each of five prototypes of such source, which contains more than 0.005 microcurie of americium-241, as follows:

(a) *Initial measurement.* The quantity of radioactive material deposited on the source shall be measured by direct counting of the source.

(b) *Dry wipe test.* The entire radioactive surface of the source shall be wiped with filter paper with the application of moderate finger pressure. Removal of radioactive material from the source shall be determined by measuring the radioactivity on the filter paper or by direct measurement of the radioactivity on the source following the dry wipe.

(c) *Wet wipe test.* The entire radioactive surface of the source shall be wiped with filter paper, moistened with water, with the application of moderate finger pressure. Removal of radioactive material from the source shall be determined by measuring the radioactivity on the filter paper after it has dried or by direct measurement of the radioactivity on the source following the wet wipe.

(d) *Water soak test.* The source shall be immersed in water at room temperature for a period of 24 consecutive hours. The source shall then be removed from the water. Removal of radioactive material from the source shall be determined by direct measurement of the radioactivity on the source after it has dried or by measuring the radioactivity in the residue obtained by evaporation of the water in which the source was immersed.

30 FR 8185

(e) *Dry wipe test.* On completion of the preceding tests in this section, the dry wipe test described in paragraph (b) of this section shall be repeated.

(f) *Observations.* Removal of more than 0.005 microcurie of radioactivity in any test prescribed by this section shall be cause for rejection of the source design. Results of prototype tests submitted to the Commission shall be given in terms of radioactivity in microcuries and percent of removal from the total amount of radioactive material deposited on the source.

§ 32.103 Schedule D—Prototype tests for ice detection devices containing strontium-90.

An applicant for a license pursuant to § 32.61 shall conduct prototype tests on each of five prototype ice detection devices as follows:

(a) *Temperature-altitude test.* The device shall be placed in a test chamber as it would be used in service. A temperature-altitude condition schedule shall be followed as outlined in Step 1 through Step 10 of § 32.101(a).

(b) *Vibration tests.* The device shall be subjected to vibration tests as set forth in § 32.101(b).

30 FR 9904

(c) *Shock test.* The device shall be subjected to shock test as set forth in § 32.101(d).

(d) *Hermetic seal and waterproof test.* On completion of all other tests prescribed by this section, the device shall be immersed in 30 inches of water for 24 hours and shall show no visible evidence of physical contact between the water and the strontium-90. Absolute pressure of the air above the water shall then be reduced to 1 inch of mercury. Lowered pressure shall be maintained for 1 minute or until air bubbles cease to be given off by the water, whichever is the longer. Pressure shall then be increased to normal atmospheric pressure. Any visible evidence of physical contact between the water and the strontium-90 shall be considered leakage.

(e) *Observations.* After each of the tests prescribed by this section, each device shall be examined for evidence of physical damage and for loss of strontium-90. Any evidence of leakage or damage to or failure of any device which could affect containment of the strontium-90 shall be cause for rejection of the design if the damage or failure is attributable to a design defect. Loss of strontium-90 from each tested device shall be measured by wiping with filter paper an area of at least 100 square centimeters on the outside surface of the device, or by wiping the entire surface area if it is less than 100 square centimeters. The amount of strontium-90 in the water used in the hermetic seal and waterproof test prescribed in paragraph (d) of this section shall also be measured. The detection on the filter paper of more than 2,200 disintegrations per minute of strontium-90 per 100 square centimers of surface wiped or in the water of more than 0.1 percent of the original amount of strontium-90 in any device, shall be cause for rejection of the tested device.

30 FR 9904

Subpart C—Acceptance Sampling Procedures

§ 32.110 Acceptance sampling procedures under certain specific licenses.

(a) A random sample shall be taken from each inspection lot of devices licensed under §§ 32.14, 32.53, or 32.61 for which testing is required pursuant to §§ 32.15, 32.55, or 32.62 in accordance with the appropriate Sampling Table in this section determined by the designated Lot Tolerance Percent Defective. If the number of defectives in the sample does not exceed the acceptance number in the appropriate Sampling Table in this section, the lot shall be accepted. If the number of defectives in the sample exceeds the acceptance number in the appropriate Sampling Table in this section, the entire inspection lot shall be rejected.

(b) Single sampling tables for Lot Tolerance Percent Defective:

(1) Lot Tolerance Percent Defective 0.5 percent:

Lot size	Sample size	Acceptance No.
1 to 180----------	All	0
181 to 210 --------	180	0
211 to 250 --------	210	0
251 to 300 --------	240	0
301 to 400 --------	275	0
401 to 500 --------	300	0
501 to 600 --------	320	0
601 to 800 --------	350	0
801 to 1,000 -------	365	0
1,001 to 2,000 -----	410	0
2,001 to 3,000 -----	430	0
3,001 to 4,000 -----	440	0
4,001 to 5,000 -----	445	0
5,001 to 7,000 -----	450	0
7,001 to 10,000 ----	455	0
10,001 to 20,000 ---	460	0
20,001 to 50,000 ---	775	1
50,001 to 100,000---	780	1

(2) Lot Tolerance Percent Defective 1.0 percent:

39 FR 22129

Lot size	Sample size	Acceptance No.
1 to 120----------	All	0
121 to 150 --------	120	0
151 to 200 --------	140	0
201 to 300 --------	165	0
301 to 400 --------	175	0
401 to 500 --------	180	0
501 to 600 --------	190	0
601 to 800 --------	200	0
801 to 1,000 -------	205	0
1,001 to 3,000 -----	220	0
3,001 to 5,000 -----	225	0
5,001 to 10,000 ----	230	0
10,001 to 100,000---	390	1

(3) Lot Tolerance Percent Defective 2.0 percent:

Lot size	Sample size	Acceptance No.
1 to 75 ---------	All	0
76 to 100 --------	70	0
101 to 200 --------	85	0
201 to 300 --------	95	0
301 to 400 --------	100	0
401 to 600 --------	105	0
601 to 800 --------	110	0
801 to 4,000 -------	115	0
4,001 to 10,000 ----	195	1
10,001 to 100,000---	200	1

39 FR 22129

(4) Lot Tolerance Percent Defective 3.0 percent:

Lot size	Sample size	Acceptance No.
1 to 40	All	0
41 to 55	40	0
56 to 100	55	0
101 to 200	65	0
201 to 500	70	0
501 to 3,000	75	0
3,001 to 100,000	130	1

(5) Lot Tolerance Percent Defective 4.0 percent:

Lot size	Sample size	Acceptance No.
1 to 35	All	0
36 to 50	34	0
51 to 100	44	0
101 to 200	50	0
201 to 2,000	55	0
2,001 to 100,000	95	1

(6) Lot Tolerance Percent Defective 5.0 percent:

Lot size	Sample size	Acceptance No.
1 to 30	All	0
31 to 50	30	0
51 to 100	37	0
101 to 200	40	0
201 to 300	43	0
301 to 400	44	0
401 to 2,000	45	0
2,001 to 100,000	75	1

(7) Lot Tolerance Percent Defective 7.0 percent:

Lot size	Sample size	Acceptance No.
1 to 25	All	0
26 to 50	24	0
51 to 100	28	0
101 to 200	30	0
201 to 300	31	0
301 to 800	32	0
801 to 1,000	33	0
1,001 to 100,000	55	1

39 FR 22129

(8) Lot Tolerance Percent Defective 10.0 percent:

Lot size	Sample size	Acceptance No.
1 to 20	All	0
21 to 50	17	0
51 to 100	20	0
101 to 200	22	0
201 to 800	23	0
801 to 100,000	39	1

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[Note removed 49 FR 19623]

PART 32

SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

PROPOSED RULE MAKING

45 FR 70874
Published 10/27/80
Comment period expires 12/11/80

Exemption of Technetium-99 and Low-Enriched Uranium as Residual Contamination in Smelted Alloys

See Part 30 Proposed Rule Making

50 FR 30616
Published 7/26/85
Comment period expires 11/18/85

Medical Use of Byproduct Material

See Part 35 Proposed Rule Making

UNITED STATES NUCLEAR REGULATORY COMMISSION

RULES and REGULATIONS

TITLE 10, CHAPTER 1, CODE OF FEDERAL REGULATIONS—ENERGY

PART 32

SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

STATEMENTS OF CONSIDERATION

30 FR 8185
Published 6/26/65
Effective 8/25/65

See Part 30 Statements of Consideration.

30 FR 9904
Published 8/10/65
Effective 9/9/65

General License for Strontium-90 in Ice Detection Devices

See Part 31 Statements of Consideration.

31 FR 5315
Published 4/2/66
Effective 5/2/66

Exemption of Tritium Contained in Certain Items

See Part 30 Statements of Consideration.

32 FR 4241
Published 3/18/67
Effective 4/17/67

Exemption of Scandium-46-Labeled Resins for Use in Oil Wells

See Part 30 Statements of Consideration.

33 FR 6462
Published 4/27/68
Effective 5/27/68

Increase in Quantity Limit for Promethium-147 in Generally Licensed Luminous Aircraft Safety Devices

See Part 31 Statements of Consideration.

33 FR 16330
Published 11/7/68
Effective 12/7/68

Labeling Requirements for Luminous Aircraft Safety Devices Used Under General License

On June 5, 1968, the Atomic Energy Commission published in the FEDERAL REGISTER (33 F.R. 8350) a proposed amendment to its regulation 10 CFR Part 32, "Specific Licenses to Manufacture, Distribute, or Import Exempted and Generally Licensed Items Containing Byproduct Material", which would amend the labeling requirements for luminous aircraft safety devices used under the general license in § 31.7, 10 CFR Part 31, "General Licenses for Certain Quantities of Byproduct Material and Byproduct Material Contained in Certain Items". Such devices are required to be labeled in accordance with the requirements of § 32.54, 10 CFR Part 32.

The labeling which would be required by the proposed amendment to § 32.54 would omit specific reference to § 31.7 and, following similar amendment of of Agreement State regulations, could be appropriately used on luminous aircraft safety devices within either Agreement States or non-Agreement States.

Interested persons were invited to submit written comments and suggestions for consideration in connection with the proposed amendment within 30 days after publication of the notice of proposed rule making in the FEDERAL REGISTER. After consideration of the comments received and other factors involved, the Commission has adopted the amendment set out below

The text of the amendment adopted differs from the text of the proposed amendment published June 5, 1968, in that a requirement to specify a device serial number has been added, minimum labeling on each device has been specified, and the minimum content of a leaflet enclosed in or accompanying the container in which a device is shipped has been prescribed. Minor editorial changes have also been made.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendment to title 10, Chapter I, Code of Federal Regulations, Part 32, is published as a document subject to codification effective thirty (30) days after publication in the FEDERAL REGISTER.

33 FR 16553
Published 11/14/68
Effective 1/13/69

General License for Use of Iodine-125 or Iodine-131 for In Vitro Clinical or Laboratory Testing

See Part 31 Statements of Consideration.

34 FR 6651
Published 4/18/69
Effective 5/18/69

Exemption of Electron Tubes

See Part 30 Statements of Consideration.

34 FR 6653
Published 4/18/69
Effective 5/18/69

PART 30—RULES OF GENERAL APPLICABILITY TO LICENSING OF BYPRODUCT MATERIAL

PART 32—SPECIFIC LICENSES TO MANUFACTURE, DISTRIBUTE, OR IMPORT EXEMPTED AND GENERALLY LICENSED ITEMS CONTAINING BYPRODUCT MATERIAL

Exemption of Byproduct Material in Gas and Aerosol Detectors

On November 1, 1968, the Atomic Energy Commission published in the FEDERAL REGISTER (33 F.R. 16089) proposed amendments to its regulations, 10 CFR Parts 30 and 32, which would exempt from licensing and regulatory requirements the use of byproduct material in gas and aerosol detectors and would establish safety criteria that manufacturers and importers of such detectors would be required to meet.

To assure that exempt detectors meet the criteria, manufacturers and importers would be permitted to distribute them only under conditions of specific licenses issued by the Commission. The proposed amendments, in effect, make the manufacturer or importer responsible for providing a product which meets specified safety requirements so that regulation of the user is not necessary.

Interested persons were invited to submit written comments and suggestions for consideration in connection with the proposed amendments within 60 days after publication of the notice of proposed rule making in the Federal Register.

After consideration of the comments and other factors involved, the Commission has adopted the amendments set forth below. The only changes from the proposed amendments, other than editorial and clarifying changes, are:

(a) In the description of the information as to radiation levels for detectors required to be submitted by an applicant for a specific license under Part 32, the distances for measurement of radiation levels have been changed from 1 and 10 centimeters to 5 and 25 centimeters from the surface of the detector, and a provision for averaging the radiation level over an area not to exceed 10 square centimeters has been added (§ 32.26(b)(6));

(b) In the safety criteria for detectors, the limits for dose or dose commitment to any individual under normal and the most severe conditions, such as accidents or fires, have been restated in an expanded § 32.27(c) in terms of the probability of the failure of the detector under such circumstances that a person would receive a dose or dose commitment in excess of the specified limits; and

(c) A new item has been added, in § 32.26(b)(14), to the information required to be submitted by an applicant for a specific license, to require such applicant to show that the probabilities, with respect to the doses referred to in § 32.27(c) meet the criteria of that paragraph.

The amendments set forth below also include a definition of the term "dose commitment" (§ 32.2(a)). This term was used in the proposed amendments to exempt from regulatory controls the use of byproduct material in gas and aerosol detectors and has been defined (33 F.R. 9198) as part of the proposed exemption for tritium, krypton-85, and promethium-147 in self-luminous products, published June 21, 1968.

The Commission has found that, under the conditions specified in the amendments, the exemption will not constitute an unreasonable risk to the common defense and security and to the health and safety of the public.

Petitions for rule making for exemption of gas and aerosol detectors which do not meet the conditions of the amendments (§§ 32.26 and 32.27) will be considered on a case-by-case basis.

Under the provisions of § 150.15(a)(6) of 10 CFR Part 150, "Exemptions and Continued Regulatory Authority in Agreement States Under Section 274," the transfer of possession or control by the manufacturer, processor, or producer of products distributed for use under the exemption would be subject to the Commission's licensing and regulatory requirements even if the product is manufactured pursuant to an Agreement State license.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter 1, Code of Federal Regulations, Parts 30 and 32, are published as a document subject to codification, to be effective thirty (30) days after publication in the Federal Register.

34 FR 9025
Published 6/6/69
Effective 7/5/69

Exemption of Tritium, Krypton-85, and Promethium-147 in Self-Luminous Products

See Part 30 Statements of Consideration.

35 FR 6426
Published 4/22/70
Effective 5/22/70

See Part 30 Statements of Consideration.

35 FR 6703
Published 4/28/70
Effective 7/1/70

Reporting Requirements

On January 9, 1970, the Atomic Energy Commission published in the Federal Register (35 F.R. 362) proposed amendments to its regulation 10 CFR Part 32 which would amend the reporting requirements applicable to licensees who import or transfer byproduct material for use under the exemptions from licensing requirements set out in §§ 30.14, 30.15, 30.16, 30.19, and 30.20.

The proposed amendments of §§ 32.16, 32.25, and 32.29 would require licensees to report annually the total quantity of each byproduct material imported or transferred in each type of exempt item, and the total number of each exempt item imported or transferred during the reporting period.

The present text of §§ 32.12, 32.16, 32.25, and 32.29 does not clearly require the filing of a report if no imports or transfers of byproduct material have been made during the reporting period. In order that the Commission will have a complete record of all imports or transfers of byproduct material in exempt items, the proposed amendments would also require the licensee to file a report which would furnish the specified information or state that no imports or transfers of byproduct material in exempt items were made during the reporting period.

Under the proposed amendments a person who imports a product for sale or distribution may report either the import or the subsequent transfer of the product. The proposed amendments of §§ 32.12, 32.16, 32.25, and 32.29 also include minor editorial changes which are made for clarity and uniformity of language.

Interested persons were invited to submit written comments and suggestions for consideration in connection with the proposed amendments within 60 days after publication of the notice of proposed rule making in the Federal Register.

After consideration of the comments the Commission has adopted the proposed amendments. The text of the amendments set out below is identical with the text of the proposed amendments published on January 9, 1970.

In some instances a manufacturer or importer may consider the information furnished to the Commission under the reporting requirements to be proprietary data and may wish to request the Commission to withhold such information from public disclosure. A request for withholding should be made in accordance with the procedures set out in § 2.790 of the Commission's rules of practice, 10 CFR Part 2.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 32, are published as a document subject to codification to become effective on July 1, 1970.

38 FR 29314
Published 10/24/73
Effective 10/24/73

Definitions of Units of Radioactivity

See Part 20 Statements of Consideration.

38 FR 34110
Published 12/11/73
Effective 1/10/74

General License for Use of Carbon-14 for In Vitro Clinical or Laboratory Testing

See Part 31 Statements of Consideration.

39 FR 22129
Published 6/20/74
Effective 7/22/74

Revisions of Quality Assurance Practices

The Atomic Energy Commission has revised acceptance sampling procedures for persons specifically licensed under 10 CFR Part 32 to manufacture, distribute, or import exempted and generally licensed items containing byproduct material. As revised, the acceptance sampling procedures in § 32.110 are based on the concept of Lot Tolerance Percent Defective (LTPD) which is defined in new § 32.2(b) as, expressed in percent defective, the poorest quality in an individual inspection lot that should be accepted.

Conforming amendments of §§ 32.15, 32.55, and 32.62 provide assurance that persons licensed under §§ 32.14, 32.53, or 32.61 will for LTPD of 5.0 percent accept or reject inspection lots of products in accordance with the directions of § 32.110. In addition, the amendments provide that the Commission will approve alternative procedures if the applicant for a license demonstrates that the alternative procedures provide the equivalent of LTPD 5.0 percent.

The effect of the amendments is to provide uniform protection against the acceptance of poor quality lots. For example, a 50-item inspection lot containing 5.0 percent defectives would have the same chance, one chance in ten, of being accepted as a 100,000-item inspection lot containing 5.0 percent defectives.

The sampling table for LTPD 5.0 percent is consistent with Sampling Table A, lot size 1301 to 3200, previously set out in § 32.110. With regard to protection as a function of lot size, a mathematical analysis has demonstrated that Sampling Table A previously set out in § 32.110, even though based on an Acceptable Quality Level of 1 percent defective, had one chance in ten of accepting 4 percent defectives in a lot size of 22,000 and one chance in ten of accepting 14 percent defectives in a lot size of 110.

In anticipation of additional products being subjected to acceptance sampling procedures in 10 CFR Part 32, eight single sampling tables covering the range of 0.5 percent to 10.0 percent LTPD are set out in § 32.110(b), any one of which may be referenced depending on the percent defectives that can be tolerated in inspection lots of the product under consideration.

Inasmuch as the amendments set forth below are of a minor nature, good cause exists for omitting notice of proposed rule making, and public procedure thereon, as unnecessary.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 32 are published as a document subject to codification.

39 FR 26143
Published 7/17/74
Effective 8/16/74 (Parts 31 & 32)
Effective 1/13/75 (Part 35)

Group Licensing for Certain Medical Uses

See Part 35 Statements of Consideration.

39 FR 26397
Published 7/19/74
Effective 7/19/74

Revisions of Quality Assurance Practices; Corrections

In FR Doc. 74-14090, appearing at page 22129 in the issue for June 20, 1974, the following changes should be made.

39 FR 43531
Published 12/16/74
Effective 1/15/75

PART 31—GENERAL LICENSES FOR BYPRODUCT MATERIAL

PART 32—SPECIFIC LICENSES TO MANUFACTURE, DISTRIBUTE, OR IMPORT CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

Revision of General License for Industrial Devices

The Atomic Energy Commission published in the FEDERAL REGISTER on February 5, 1974 (39 FR 4583) proposed amendments to its regulations pertaining to the use of byproduct material in certain gauges and similar devices. The proposed amendments, among other things, would have required the user to register with the Commission prior to receiving byproduct material for use under the general license in § 31.5 of the Commission's regulation, 10 CFR Part 31, "General Licenses for Byproduct Material." Related changes were proposed in the requirements imposed on persons specifically licensed under 10 CFR 32.51 to distribute byproduct material in devices to be used under the general license.

Interested persons were invited to submit written comments on the proposed amendments by March 18, 1974. That date was later extended to April 17, 1974, and on April 16, 1974, a public meeting on the proposed changes was held at the Atomic Energy Commission's offices in Bethesda, Maryland. After consideration of the written comments received, the record of the public meeting, and other factors involved, the Commission has adopted the proposed amendments with certain modifications. The more significant ones are described below.

(1) Under the proposed amendments, each user of the general license would have been identified to the Commission by the registration certificate which he filed prior to receipt of a device containing byproduct material. Under the amendments set out below, prior registration by the general licensee is not required. Persons receiving devices for use under 10 CFR 31.5 will be identified in quarterly reports submitted to the Commission by persons specifically licensed to distribute the devices. Persons specifically licensed under 10 CFR 32.51 also will be required to report to the appropriate Agreement State agency any transfers to general licensees regulated by the Agreement State. Implementation of similar reporting requirements by the Agreement States should result in a system whereby all transfers to persons using the general license in 10 CFR 31.5 or equivalent Agreement State regulations are reported to the responsible regulatory agency.

(2) The proposed amendments would have permitted transfer of devices between general licensees since both the transferor and the transferee would have registered with the Commission. Since prior registration by the general licensee has not been adopted, the proposed provision for transfer by the general licensee has been modified in order to achieve a workable system for identifying users under the general license. The amendments set out below permit the general licensee to transfer a device (a) to a specific licensee, (b) to another general licensee if the device remains installed in the same location but the person possessing the device changes as may be the case when a plant or building is sold, and (c) to another general licensee when possession of a device which remains in its shipping container is changed as in the case when a distributor ships a device to a construction site where it may be temporarily possessed by the building contractor prior to possession by the ultimate user.

(3) The proposed amendments provided that under certain conditions the general licensee may be authorized to perform tests for leakage of radioactive material. Under the amendments set out below the general licensee would only be authorized to collect the test sample for the leakage test; this sample would then be analyzed by a specific licensee.

(4) The proposed amendments would have deleted an existing specific requirement that the general licensee have the device tested periodically for proper operation of the on-off mechanism and indicator. The intent of the proposed deletion was not to eliminate all tests on on-off mechanisms and indicators but rather to consider the need and procedures for the tests on a case-by-case basis. That consideration would have been reflected in the safety instructions and precautions which the user would be required to follow and those instructions could require that the tests be performed by a specific licensee. Comments on the proposed deletion of the specific test requirement, however, indicate that such action could result in misunderstanding and non-performance of important safety testing. Accordingly, the amendments set out below retain a specific requirement for testing of the on-off mechanism and indicator.

(5) Under the proposed amendments, the general license in § 31.5 would have been restricted to commercial and industrial firms, research, education and medical institutions, and governmental agencies. The amendments set out below also extend the general license to individuals using the devices in the course of their work, occupation, or profession. An example of such an individual is a consulting engineer who owns and uses a soil density gauge in his work on highway construction projects.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to 10 CFR Parts 31 and 32 are published as a document subject to codification.

41 FR 16445
Published 4/19/76
Effective 4/19/76

Miscellaneous Changes to Chapter

See Part 20 Statements of Consideration.

41 FR 18300
Published 5/3/76
Effective 6/2/76

Preservation of Records

See Part 20 Statements of Consideration.

42 FR 21604
Published 4/28/77
Effective 5/31/77

Addition to General License for In Vitro Diagnostic Products

See Part 31 Statements of Consideration.

42 FR 26986
Published 5/26/77
Effective 6/27/77

Addition to General License for In Vitro Diagnostic Products

See Part 31 Statements of Consideration.

43 FR 6915
Published 2/17/78
Effective 5/3/78

Export and Import of Nuclear Facilities and Materials

See Part 110 Statements of Considerations.

44 FR 50324
Published 8/28/79
Effective 9/27/79

Additions of Veterinarians to the In Vitro General License

See Part 31 Statements of Consideration.

45 FR 38340
Published 6/9/80
Effective 1/1/81

Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to provide new requirements for labeling of gas and aerosol detectors, including smoke detectors, and also for labeling the point-of-sale packaging for these detectors. The new requirements are intended to: (1) inform prospective purchasers and other persons that the detectors contain radioactive material, and (2) identify the radioactive material and quantity of activity in each detector.

EFFECTIVE DATE: January 1, 1981.

FOR FURTHER INFORMATION CONTACT: Donovan A. Smith, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone 301-443-5946.

SUPPLEMENTARY INFORMATION: On November 30, 1979, the NRC published in the **Federal Register** (44 FR 68853) a notice of proposed amendments to 10 CFR Part 32 to revise NRC requirements for labeling of gas and aerosol detectors designed to protect life or property from fires and airborne hazards. These detectors include smoke detectors. Smoke detectors containing small quantities of radioactive material, usually americium-241, are distributed extensively to homeowners and commercial and industrial users. The homeowner or other user is exempt from regulatory requirements; the manufacturer (or distributor of imported detectors) must have a specific license from the NRC to distribute the detector. The manufacturer of the detector has been required to label the detector in such a way that the manufacturer and the radioactive material can be identified. This final rule, in addition, requires the manufacturer to label the package used in the retail sale of the detector. This new requirement for labeling of the package in which the detector is displayed for sale is intended to inform prospective buyers that the detector contains radioactive material.

The notice of proposed rulemaking provided a period of 45 days for public comment. Copies of a value/impact assessment of the proposed amendments, prepared by the NRC staff, were sent to individuals who requested further information.

Interested persons submitted 24 letters regarding the proposed amendments. The letters generally included numerous specific comments but the most frequent and key comments could be divided into three categories:

1. The use of radioactive material in smoke detectors should be banned because there are nonradioactive detectors available; however, if radioactive smoke detectors are permitted to be used, they should be disposed of in a controlled manner as radioactive waste and should not be discarded with normal household waste.

2. The proposed amendments should not be made effective because the new labels would not be understood, would cause unnecessary concern on the part of the consumer, and would discourage the sale of a lifesaving device.

3. The proposed statement to be included on the label for the package containing the detector, "This detector contains radioactive material which presents no significant hazard to health if used in accordance with the instructions," is misleading and should be revised.

Copies of the comments may be examined in the Commission's Public Document Room at 1717 H Street, NW., Washington, D.C. A summary of the NRC's response to these comments is presented below.

1. The principal question in this rulemaking is neither prohibition of the use of smoke detectors nor their disposal. The question is how to label the detector package so that prospective purchasers are informed that the detectors contain radioactive material and are informed about what and how much radioactive material is contained in the detectors.

2. Whether or not some persons may or may not understand the significance of the information required in the new labels, and whether or not sales may or may not be discouraged, it appears appropriate to provide the prospective purchaser/user an opportunity to be informed about the radioactive content of the detector. If that person then decides to reject the benefit because of the small radiation risk, if any, associated with the detector, that

3. The NRC agrees that revision of the proposed statement is needed to avoid unintended meanings. For example, the statement could reasonably cause one to believe that there would be a significant hazard to health if the detector is used other than in accordance with the instructions.

Upon further consideration of the objective of conveying safety information to the prospective purchaser, the NRC has revised the statement to show that the detector contains radioactive material, that the detector has been manufactured in compliance with safety criteria of the U.S. Nuclear Regulatory Commission, and that the user of the detector is exempt from U.S. NRC regulations.

This method of communicating safety information to consumers by citing an applicable Federal regulation is used for other radiation-emitting consumer products. For example, the U.S. Department of Health and Human Services requires that certification tags which give indication of product conformance to applicable Federal standards be attached to television receivers and microwave ovens. The fact that a product's manufacture is subject to Federal standards and regulation by a Federal agency may be significant to the prospective purchaser.

After careful consideration of the comments on the notice of proposed rulemaking and the other factors involved, the Commission has adopted the rule in effective form with the significant changes discussed below.

1. The proposed amendments would have required package labeling only if the detector were individually packaged. The final rule does not limit package labeling to individually packaged detectors. Although individual packaging is most frequently used in marketing of detectors intended for residential use, many detectors intended for commercial and industrial establishments are not individually packaged. An opportunity for informing this latter group of users will be provided by the requirement that all point-of-sale packages be labeled.

2. The proposed amendments would have been effective after July 14, 1980. The final rule becomes effective January 1, 1981. This change is based on industry's representations that additional time is needed to avoid dumping of present supplies of labels and to design and produce new labels. Also, no safety question in need of immediate action is involved in this change in the effective date.

3. The proposed amendments would have required the detector label to identify the manufacturer or initial transferor of the product. The final rule requires both the detector label and the package label to identify the person with an NRC license authorizing distribution of the detectors. Usually that person is the manufacturer if the detector is made in the U.S., or the importer if the detector is manufactured abroad. In either case, identification of the NRC licensee will assure identification of the person with responsibility for distributing a product that meets NRC safety criteria.

4. The proposed amendments would have required that the detector label be located on the external surface of the detector. The final rule retains that requirement and also specifies that the label must be visible when the detector is removed from its mounting, i.e., from its installed position. This additional detail on location of the detector label was prompted by several comments about the need for the label to be visible when the detector is installed. Because of the safety criteria that each detector must meet, particularly those relating to external radiation levels, and because of the other provisions for location of labels, a highly visible label on the external surface of an installed detector is not needed.

5. The proposed amendments would have required that the label on the point-of-sale package contain the statement "This detector contains radioactive material which presents no significant hazard to health if used in accordance with the instructions." The final rule does not require that statement. As discussed before, the point-of-sale package label will state that the detector contains radioactive material, that it has been produced in compliance with NRC safety criteria, and that the purchaser is exempt from any regulatory requirements.

6. The proposed amendments would not have changed a general provision whereby the Commission, on a case-by-case basis, may require the manufacturer to provide additional labeling or marking information, including disposal instructions when appropriate. The final rule changes this provision. The final rule omits specific reference to disposal instructions in order to avoid any suggestion that the labeling or marking imposes regulatory requirements on the consumer. The labeling or marking is intended only to inform the consumer.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 32 are published as a document subject to codification to be effective January 1, 1981.

≫48 FR 12331
Published 3/24/83
Effective 6/30/83

10 CFR Part 32

Consumer Products Containing Small Quantities of Radioactive Material; Modified Reporting and Recordkeeping Requirements

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to modify the reporting and recordkeeping requirements imposed on persons specifically licensed to distribute consumer products containing byproduct material. The existing annual reporting requirements are amended to require that reports be submitted (1) every five years, or (2) at the time of application for renewal of the specific license, or (3) at the time the licensee notifies the Commission that it is discontinuing distribution of these consumer products. The amendment is intended to reduce the number of reports submitted to the Commission. This amendment pertains only to the submission of reports and recordkeeping requirements and will not affect the safety properties of the products that are distributed.

EFFECTIVE DATE: June 30, 1983.

FOR FURTHER INFORMATION CONTACT: Dr. Anthony N. Tse, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555 (301-443-5825).

SUPPLEMENTARY INFORMATION:

Background

On November 23, 1982, the NRC published in the Federal Register (47 FR 52719) a Notice of Proposed Rulemaking to amend 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or

Transfer Certain Items Containing Byproduct Material." The proposed amendments to Part 32 suggested modifications to the reporting and recordkeeping requirements imposed on persons licensed to distribute consumer products containing small quantities of byproduct material (exempt items).

These regulations required licensees to submit an annual report to the NRC specifying the total quantity of byproduct material transferred in each type of consumer product and the total number of each product transferred during the reporting period. An annual report was required even if a licensee made no transfers during the reporting period. This process provided the NRC and other interested parties with information concerning the extent and pattern of consumer product distribution. The NRC has also used this information to estimate the exposure of the general public to radiation from these products.

After reviewing these reporting requirements, the NRC proposed a minor change to the requirements that would reduce paperwork burdens on the affected licensees and the agency without diminishing the value of these reports to the NRC's regulatory program. The NRC proposed that the licensees be required to submit a report every 5 years, or at the time of application for renewal of the specific license, or at the time the licensee notifies the Commission that it is discontinuing distribution of these consumer products. In the notice of proposed rulemaking, the NRC also sought public comment on two alternative actions: (1) Eliminating reporting requirements completely, and (2) establishing a threshold such that if less than 1000 units were distributed annually, a report would not be required. However, the NRC has decided to adopt the approach set out in the proposed rule. The reason for this decision is outlined in the NRC's response to comments received on the proposed rule and the suggested alternatives.

The requirements for the type of records that must be kept is not changed although in certain cases the length of time that these records must be stored is modified to conform with the 5 year reporting period. This is necessary to facilitate the licensee's preparation of summary reports.

Comments

Interested persons were invited to submit written comments. The 30-day comment period expired on December 23, 1982. Eleven letters of comment were received: ten from private industry and one from a state agency.

Most commenters supported the Commission's effort to reduce the reporting burden on licensees. However, the commenters varied in their views as to which alternative action should be taken. One suggested that the NRC terminate licensing for small distributors of consumer products; four favored complete elimination of reporting requirements; three supported the 5-year reporting period but two of these three also favored eliminating the reporting requirements; two preferred a threshold number and one opposed any change to the existing regulations.

Copies of the comments may be examined in the Commission's Public Document Room at 1717 H Street NW, Washington, DC. A summary of the comments and the NRC staff's responses to these comments is presented below.

1. Most commenters supported complete elimination of reporting requirements because (1) the public exposure to radiation from consumer products is very small and (2) the data contained in the reports could be obtained by other means, such as literature searches or discussions with product manufacturers. Although the public exposure to radiation from consumer products is very small, the Commission must, from time to time, reassess the exposure and verify that the public exposure remains small. Relatively current and accurate data on the types and quantities of products and radionuclides distributed are necessary to inform the Commission of the extent of the distribution of these products and to provide data for performing adequate assessments of public exposure to radiation from these products. Thus, the Commission believes a reasonably accurate data base should be collected by the Commission.

The Commission considered alternative ways of collecting the necessary data. Some data may be collected by literature search or by discussions with product distributors or manufacturers. However, these methods may have the following drawbacks (1) certain information, such as the number of products distributed in a year, might not be available in the literature because of its proprietary nature, (2) the data collected could have a large degree of uncertainty unless information from all licensees who distribute the products is included, and (3) the efforts spent by licensees to locate and report distribution data in response to an unscheduled data collection survey might be more burdensome than the efforts required to prepare one report every five years. Therefore the Commission believes the data obtained from reports submitted at 5-year intervals is more accurate than data collected from literature search or by discussion with manufacturers.

2. One commenter suggested that the NRC should terminate licensing small distributors of consumer products containing byproduct materials. The principal issue in this rulemaking is not whether the NRC should continue to license consumer product distributors; the issue is whether the NRC should modify its existing reporting requirements applicable to this group of licensees. Thus, this comment is not relevant to the issue in this rulemaking proceeding.

3. Two commenters preferred the alternative that would establish a threshold number for the submission of an annual report. Another commenter, on the other hand, stated that a 1000-unit threshold plan would eliminate very few smoke detector manufacturers because it is unlikely that someone would handle such a small number of products. Although the 1000-unit threshold option would result in about 30% reduction in the number of reports, it would also have three major drawbacks: (1) The data would be relatively inaccurate because it is uncertain what percent of the total would be reported, (2) the licensees would still have to summarize product distribution data at the end of a reporting period so that they could determine whether the distribution exceeded the threshold number, and (3) lack of the report from a specific licensee would lead to the uncertainty whether the threshold had not been exceeded or the licensee had neglected to file the report. On the other hand, the 5-year reporting option, as compared to the existing annual reporting requirements, would provide 80% reduction in the number of reports a licensee must submit. Therefore, the Commission believes the threshold option is not as effective in reducing the reporting burden as the 5-year reporting option.

4. One commenter suggested that the existing reporting requirements not be changed. He doubted the efficacy of the change in reducing paperwork. In addition, the turnover in personnel would make the information on a 5-year reporting interval not as valuable as it is on a yearly basis. The Commission believes that, if the reporting period is extended from 1 year to a 5-year period, there would be a significant reduction (by a factor of 5) in the number of reports that must be prepared by licensees. Although the Commission agrees that the information obtained at

5-year reporting intervals would not be as current as the information contained in annual reports, the lack of data on the yearly basis would have little impact in the NRC's effort in assessing of public exposure to radiation from these products because the period between assessments is usually greater than 5 years. Considering the significant reduction in the number of reports, the Commission believes it is cost effective to extend the reporting period from 1 year to 5 years.

5. Several commenters are concerned with extending the recordkeeping requirements. Two stated that the retention of records for another year would impose an additional and unwarranted cost. Another, however, stated that they keep records as live records for a year or two before these records are transferred to archival storage and that there is little difference between the storage of archival records for 3 or 6 years as long as these records do not have to be retrieved on a regular basis. This amendment requires that the record be maintained one year after that record was used in preparation of the 5-year report submitted to the Commission. The average record retention period would be 3 years. This replaces the existing record retention period of 2 years for about 25 licensees and 5 years for about 175 licensees or an average record retention period of 4.5 years, thereby resulting in an overall reduction in recordkeeping requirements. The Commission believes that, although each licensee may have different recordkeeping systems and the changes in recordkeeping requirements will have a different impact on various licensees, the burden on recordkeeping averaged over all the affected licensees would result in a slight reduction in the record retention periods.

The Regulation

The final rule is the same as the proposed rule. It modifies the reporting and recordkeeping requirements in 10 CFR 32.12, 32.16, 32.20, 32.25, and 32.29.

Paperwork Reduction Act Statement

The rule was submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act (Pub. L. 96-511; 42 U.S.C. Ch. 15). The information collection requirements contained in this regulation were approved by OMB. OMB approval No. 3150-0001.

Regulatory Flexibility Certification

Since these amendments generally would reduce present recordkeeping and reporting requirements, the Commission, in accordance with sec. 605(b) of the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), hereby certifies that this rule will not have a significant economic impact on a substantial number of small entities. Persons specifically licensed to distribute consumer products containing byproduct material will no longer be required to submit an annual report to the Commission but will be required to submit reports covering periods of approximately five years. An estimated reduction of about 80 percent of the approximately 200 reports currently submitted annually is expected.

List of Subjects in 10 CFR Part 32

Byproduct materials, Labeling, Nuclear materials, Penalty, Radiation protection, Reporting and recordkeeping requirements.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended and section 553 of title 5 of the United States Code the following amendment of title 10 chapter 1, Code of Federal Regulations, Part 32, is published as a document subject to codification.

48 FR 14863
Published 4/6/83

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10 CFR Part 32

Consumer Products Containing Small Quantities of Radioactive Material; Modified Reporting and Recordkeeping Requirements

Correction

In FR Doc. 83-7695 beginning on page 12331 in the issue of Thursday, March 24, 1983, make the following corrections.

1. On page 12333, first column, first line of the second paragraph of the "Authority", "sec. 23" should have read "sec. 223".

2. On the same page, second column, second line of § 32.12 (c)(2), the reference to "§ 30.27" should have read "§ 30.37".

48 FR 23383
Published 5/25/83

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10 CFR Part 32

Consumer Products Containing Small Quantities of Radioactive Material; Correction

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rulemaking; correction.

SUMMARY: This document corrects a final rule appearing in the Federal Register on March 24, 1983 (48 FR 12331) that modified reporting and recordkeeping requirements imposed on persons specifically licensed to distribute consumer products containing byproduct material. The action is necessary to correct the inadvertent omission of a reference to a section of the Commission's regulations covered by this reporting requirement.

FOR FURTHER INFORMATION CONTACT: Dr. Anthony N. Tse, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone (301) 443-5825.

1. On page 12333, second column, fourth line of § 32.16(b), the phrase "§ 30.15 or" should be inserted after the word "under."

Dated at Bethesda, Maryland, this 13 day of May, 1983

Jack W. Roe,
Acting Executive Director for Operations.

≫ 49 FR 19623
Published 5/9/84
Effective 5/9/84

Information Collection Requirements; Display of OMB Control Numbers

See Part 0 Statements of Consideration

PART 33

SPECIFIC DOMESTIC LICENSES OF BROAD SCOPE FOR BYPRODUCT MATERIAL★

Sec.
33.1 Purpose and scope.
33.8 Information collection requirements: OMB approval.

SPECIFIC LICENSES OF BROAD SCOPE

33.11 Types of specific licenses of broad scope.
33.12 Applications for specific licenses of broad scope.
33.13 Requirements for the issuance of a Type A specific license of broad scope.
33.14 Requirements for the issuance of a Type B specific license of broad scope.
33.15 Requirements for the issuance of a Type C specific license of broad scope.
33.16 Application for other specific licenses.
33.17 Conditions of specific licenses of broad scope.

SCHEDULES

33.100 Schedule A

AUTHORITY: Secs. 81 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended; 42 U.S.C. 2111, 2201 2232, 2233. For the purposes of sec. 223, 68 Stat. 958 as amended; 42 U.S.C. 2273, § 33.17(a) issued under sec. 161b., 68 Stat. 948; 42 U.S.C. 2201(b), unless otherwise noted.

33 FR 14579

§ 33.1 Purpose and scope.

This part prescribes requirements for the issuance of specific licenses of broad scope for byproduct material ("broad licenses") and certain regulations governing holders of such licenses. The provisions and requirements of this part are in addition to, and not in substitution for, other requirements of this chapter. In particular, the provisions of Part 30 of this chapter apply to applications and licenses subject to this part.

49 FR 19623

§ 33.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). OMB has approved the information collection requirements contained in this part under control number 3150–0015.

(b) The approved information collection requirements contained in this part appear in §§ 33.12, 33.13, 33.14 and 33.15.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In § 33.12, Form NRC–313I is approved under control number 3150–0042.

(2) In § 33.12, Form NRC–313M is approved under control number 3150–0041.

(3) In § 33.12, Form NRC–313R is approved under control number 3150–0023.

(4) In § 33.12, Form NRC–313T is approved under control number 3150–0081.

SPECIFIC LICENSES OF BROAD SCOPE

43 FR 6915

§ 33.11 Types of specific licenses of broad scope.

(a) A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use, and transfer of any chemical or physical form of the byproduct material specified in the license, but not exceeding quantities specified in the license, for purposes authorized by the Act. The quantities specified are usually in the multicurie range.

(b) A "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use, and transfer of any chemical or physical form of byproduct material specified in § 33.100, Schedule A, of this part for purposes authorized by the Act. The possession limit for a Type B broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in § 33.100, Schedule A, Column I. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in § 33.100, Schedule A, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

(c) A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use, and transfer of any chemical or physical form of byproduct material specified in § 33.100, Schedule A, for purposes authorized by the Act. The possession limit for a Type C broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in § 33.100, Schedule A, Column II. If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: For each radionuclide determine the ratio of the quantity possessed to the applicable quantity specified in § 33.100, Schedule A, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

49 FR 27923

§ 33.12 Applications for specific licenses by broad scope.

A person may file an application for specific license of broad scope in duplicate on NRC Form 313, "Application for Material License," in accordance with the provisions of § 30.32 of this chapter.

33 FR 14579

§ 33.13 Requirements for the issuance of a Type A specific license of broad scope.

An application for a Type A specific license of broad scope will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter;

(b) The applicant has engaged in a reasonable number of activities involving the use of byproduct material; and

(c) The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control, and accounting and management review that are necessary to assure safe operations, including:

(1) The establishment of a radiation safety committee composed of such persons as a radiological safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive materials;

(2) The appointment of a radiological safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiological safety matters; and

(3) The establishment of appropriate administrative procedures to assure:

(i) Control of procurement and use of byproduct material;

(ii) Completion of safety evaluations of proposed uses of byproduct material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

(iii) Review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with paragraph (c)(3)(ii) of this section prior to use of the byproduct material.

§ 33.14 Requirements for the issuance of a Type B specific license of broad scope.

An application for a Type B specific license of broad scope will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter; and

(b) The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:

(1) The appointment of a radiological safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiological safety matters; and

(2) The establishment of appropriate administrative procedures to assure:

(i) Control of procurement and use of byproduct material;

(ii) Completion of safety evaluations of proposed uses of byproduct material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

(iii) Review, approval, and recording by the radiological safety officer of safety evaluations of proposed uses prepared in accordance with paragraph (b)(2)(ii) of this section prior to use of the byproduct material.

33 FR 14579

§ 33.15 Requirements for the issuance of a Type C specific license of broad scope.

An application for a Type C specific license of broad scope will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter; and

(b) The applicant submits a statement that byproduct material will be used only by, or under the direct supervision of, individuals who have received:

(1) A college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering; and

(2) At least 40 hours of training and experience in the safe handling of radioactive materials, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of byproduct material to be used; and

(c) The applicant has established administrative controls and provisions relating to procurement of byproduct material, procedures, record keeping, material control and accounting, and management review necessary to assure safe operations.

§ 33.16 Application for other specific licenses.

An application filed pursuant to Part 30 of this chapter for a specific license other than one of broad scope will be considered by the Commission as an application for a specific license of broad scope under this part if the requirements of the applicable sections of this part are satisfied.

§ 33.17 Conditions of specific licenses of broad scope.

(a) Unless specifically authorized pursuant to other parts of this chapter, persons licensed under this part shall not: (1) Conduct tracer studies in the environment involving direct release of byproduct material; (2) receive, acquire, own, possess, use, transfer, or import devices containing 100,000 curies or more of byproduct material in sealed sources used for irradiation of materials; (3) conduct activities for which a specific license issued by the Commission under Part 32, 34, or 35 of this chapter is required; or (4) add or cause the addition of byproduct material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being.

33 FR 14579

(b) Each Type A specific license of broad scope issued under this part shall be subject to the condition that byproduct material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.

(c) Each Type B specific license of broad scope issued under this part shall be subject to the condition that byproduct material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiological safety officer.

(d) Each Type C specific license of broad scope issued under this part shall be subject to the condition that byproduct material possessed under the license may only be used by, or under the direct supervision of, individuals who satisfy the requirements of § 33.15 of this part.

SCHEDULES

§ 33.100 Schedule A.

Byproduct material	Col. I curies	Col. II curies
Antimony-122	1	0.01
Antimony-124	1	.01
Antimony-125	1	.01
Arsenic-73	10	.1
Arsenic-74	1	.01
Arsenic-76	1	.01
Arsenic-77	10	.1
Barium-131	10	.1
Barium-140	1	.01
Bismuth-210	.1	.001
Bromine-82	10	.1
Cadmium-109	1	.01
Cadmium-115m	1	.01
Cadmium-115	10	.1
Calcium-45	1	.01
Calcium-47	10	.1
Carbon-14	100	1.
Cerium-141	10	.1
Cerium-143	10	.1
Cerium-144	.1	.001
Cesium-131.	100	1.
Cesium-134m	100	1.
Cesium-134	.1	.001
Cesium-135	1	.01
Cesium-136	10	.1
Cesium-137	.1	.001
Chlorine-36	1	.01
Chlorine-38	100	1.
Chromium-51	100	1.
Cobalt-58m	100	1.
Cobalt-58	1	.01
Cobalt-60	.1	.001
Copper-64	10	.1
Dysprosium-165	100	1.
Dysprosium-166	10	.1
Erbium-169	10	.1
Erbium-171	10	.1
Europium-152 9.2 h	10	.1
Europium-152 13 y	.1	.001
Europium-154	.1	.001
Europium-155	1	.01
Fluorine-18	100	1.
Gadolinium-153	1	.01
Gadolinium-159	10	.1
Gallium-72	10	.1
Germanium-71	100	1
Gold-198	10	.1
Gold-199	10	.1
Hafnium-181	1	.01
Holmium-166	10	.1
Hydrogen-3	100	1
Indium-113m	100	1
Indium-114m	1	.01
Indium-115m	100	1
Indium-115	1	.01
Iodine-125	.1	.001
Iodine-126	.1	.001
Iodine-129	.1	.01
Iodine-131	.1	.001
Iodine-132	10	.1
Iodine-133	1	.01
Iodine-134	10	.1
Iodine-135	1	.01
Iridium-192	1	.01
Iridium-194	10	.1
Iron-55	10	.1
Iron-59	1	.01
Krypton-85	100	1
Krypton-87	10	.1
Lanthanum-140	1	.01
Lutetium-177	10	.1
Manganese-52	1	.01
Manganese-54	1	.01
Manganese-56	10	.1
Mercury-197m	10	.1
Mercury-197	10	.1
Mercury-203	1	.01
Molybdenum-99	10	.1
Neodymium-147	10	.1
Neodymium-149	10	.1
Nickel-59	10	.1
Nickel-63	1	.01
Nickel-65	10	.1
Niobium-93m	1	.01
Niobium-95	1	.01
Niobium-97	100	1.
Osmium-185	1	.01
Osmium-191m	100	1.
Osmium-191	10	.1
Osmium-193	10	.1
Palladium-103	10	.1
Palladium-109	10	.1
Phosphorus-32	1	.01
Platinum-191	10	.1
Platinum-193m	100	1.
Platinum-193	10	.1
Platinum-197m	100	1
Platinum-197	10	.1
Polonium-210	.01	.0001
Potassium-42	1	.01
Praseodymium-142	10	.1
Praseodymium-143	10	.1
Promethium-147	1	.01

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Byproduct material	Col. I curies	Col. II curies
Promethium-149	10	.1
Rhenium-186	10	.1
Rhenium-188	10	.1
Rhodium-103m	1,000	10.
Rhodium-105	10	.1
Rubidium-86	1	.01
Rubidium-87	1	.01
Ruthenium-97	100	1.
Ruthenium-103	1	.01
Ruthenium-105	10	.1
Ruthenium-106	.1	.001
Samarium-151	1	.01
Samarium-153	10	.1
Scandium-46	1	.01
Scandium-47	10	.1
Scandium-48	1	.01
Selenium-75	1	.01
Silicon-31	10	.1
Silver-105	1	.01
Silver-110m	.1	.001
Silver-111	10	.1
Sodium-24	1	.01
Strontium-85m	1,000	10.
Strontium-85	1	.01
Strontium-89	1	.01
Strontium-90	.01	.0001
Strontium-91	10	.1
Strontium-92	10	.1
Sulphur-35	10	.1
Tantalum-182	1	.01
Technetium-96	10	.1
Technetium-97m	10	.1
Technetium-97	10	.1
Technetium-99m	100	1.
Technetium-99	1	.01
Tellurium-125m	1	.01
Tellurium-127m	1	.01
Tellurium-127	10	.1
Tellurium-129m	1	.01
Tellurium-129	100	1
Tellurium-131m	10	.1
Tellurium-132	1	.01
Terbium-160	1	.01
Thallium-200	10	.1
Thallium-201	10	.1
Thallium-202	10	.1
Thallium-204	1	.01
Thulium-170	1	.01
Thulium-171	1	.01
Tin-113	1	.01
Tin-125	1	.01
Tungsten-181	1	.01
Tungsten-185	1	.01
Tungsten-187	10	.1
Vanadium-48	1	.01
Xenon-131m	1,000	10.
Xenon-133	100	1.
Xenon-135	100	1.
Ytterbium-175	10	.1
Yttrium-90	1	.01
Yttrium-91	1	.01
Yttrium-92	10	.1
Yttrium-93	1	.01
Zinc-65	1	.01
Zinc-69m	10	.1
Zinc-69	100	1.
Zirconium-93	1	.01
Zirconium-95	1	.01
Zirconium-97	1	.01
Any byproduct material other than alpha emitting byproduct material not listed above	.1	.001

[Note removed 49 FR 19623]

UNITED STATES NUCLEAR REGULATORY COMMISSION

RULES and REGULATIONS

TITLE 10, CHAPTER 1, CODE OF FEDERAL REGULATIONS—ENERGY

PART 33

SPECIFIC DOMESTIC LICENSES OF BROAD SCOPE FOR BYPRODUCT MATERIAL

STATEMENTS OF CONSIDERATION

33 FR 14579
Published 9/28/68
Effective 10/28/68

On April 30, 1968, the Atomic Energy Commission published in the Federal Register (33 F.R. 6551) a proposed revision of 10 CFR Part 33 of its regulations which would, among other things, permit the wider use of specific licenses of broad scope ("broad licenses"). Three types of broad licenses, designated "Type A", "Type B", and "Type C" specific licenses of broad scope, would be provided. The "Type A" broad licenses would be essentially the same as the broad licenses described in the present Part 33. "Type B" and "Type C" broad licenses would provide similar flexibility for specially qualified applicants with intermediate or small-scale radioisotope programs.

Interested persons were invited to submit written comments and suggestions for consideration in connection with the proposed revision within 60 days after publication of the notice of proposed rule making in the Federal Register. After consideration of the comments and other factors involved, the Commission has adopted the proposed revision. The text of the revision set out below is essentially the same as that published April 30, 1968. Sections 33.13(c)(2) and 33.14(b)(1) have been modified to require the appointment of a radiological safety officer who is qualified by training and experience in radiation protection rather than to require that he be qualified to actually use the material. Section 33.17(a)(2) has been amended to specify those types of irradiators which are not to be licensed under licenses of broad scope as "devices containing 100,000 curies or more of byproduct material in sealed sources used for irradiation of materials." The title of the committee required by § 33.13(c)(1) has been changed from "isotope committee" to "radiation safety committee."

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following revision of Title 10, Chapter I, Code of Federal Regulations, Part 33, is published as a document subject to codification, to be effective 30 days after publication in the Federal Register.

43 FR 6915
Published 2/17/78
Effective 5/3/78

Export and Import of Nuclear Facilities and Materials

See Part 110 Statements of Considerations.

49 FR 19623
Published 5/9/84
Effective 5/9/84

Information Collection Requirements; Display of OMB Control Numbers

See Part 0 Statements of Consideration

➤ **49 FR 27923**
Published 7/9/84
Effective 7/9/84

Application Consolidation to NRC Form 313; Application for Material License

See Part 30 Statements of Consideration

PART 34

LICENSES FOR RADIOGRAPHY AND RADIATION SAFETY REQUIREMENTS FOR RADIOGRAPHIC OPERATIONS

Sec.
34.1 Purpose and scope.
34.2 Definitions.
34.3 Applications for specific licenses.
34.8 Information collection requirements: OMB approval.

Subpart A—Specific Licensing Requirements

34.11 Issuance of specific licenses for use of sealed sources in radiography.

Subpart B—Radiation Safety Requirements

EQUIPMENT CONTROL

34.21 Limit on levels of radiation for radiographic exposure devices and storage containers.
34.22 Locking of radiographic exposure devices and storage containers.
34.23 Storage precautions.
34.24 Radiation survey instruments.
34.25 Leak testing, repair, tagging, opening, modification and replacement of sealed sources.
34.26 Quarterly inventory.
34.27 Utilization logs.
34.28 Inspection and maintenance of radiographic exposure devices and storage containers.
34.29 Permanent radiographic installations.

PERSONAL RADIATION SAFETY REQUIREMENTS FOR RADIOGRAPHERS AND RADIOGRAPHERS' ASSISTANT

34.31 Training.
34.32 Operating and emergency procedures.
34.33 Personnel monitoring.

PRECAUTIONARY PROCEDURES IN RADIOGRAPHIC OPERATIONS

34.41 Security.
34.42 Posting.
34.43 Radiation surveys and survey records.
34.44 Supervision of radiographers' assistants

EXEMPTIONS

34.51 Applications for exemptions.
Appendix A.

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended; 42 U.S.C. 2111, 2201, 2232, 2233. For the purposes of sec. 223, 68 Stat. 958, as amended, 42 U.S.C. 2273, §§ 34.11(d), 34.25(c), 34.26, 34.27, 34.28(b), 34.29(c), 34.31(c), 34.33(b), 34.33(e), and 34.43(c) issued under sec. 161o, 68 Stat. 950, as amended, 42 U.S.C. 2201(o), unless otherwise noted.

§ 34.1 Purpose and scope.

This part prescribes requirements for the issuance of licenses for the use of sealed sources containing byproduct material and radiation safety requirements for persons using such sealed sources in radiography. The provisions and requirements of this part are in addition to, and not in substitution for, other requirements of this chapter. In particular, the provisions of Part 30 of this chapter apply to applications and licenses subject to this part. Nothing in this part shall apply to uses of byproduct material for medical diagnosis or therapy.

§ 34.2 Definitions.

As used in this part:

(a) "Radiography" means the examination of the structure of materials by nondestructive methods, utilizing sealed sources of byproduct materials;

(b) "Radiographer" means any individual who performs or who, in attendance at the site where the sealed source or sources are being used, personally supervises radiographic operations and who is responsible to the licensee for assuring compliance with the requirements of the Commission's regulations and the conditions of the license;

30 FR 8185

(c) "Radiographer's assistant" means any individual who, under the personal supervision of a radiographer, uses radiographic exposure devices, sealed sources or related handling tools, or radiation survey instruments in radiography;

(d) "Radiographic exposure device" means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure;

(e) "Sealed source" means any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material;

(f) "Storage container" means a device in which sealed sources are transported or stored.

30 FR 8185

(g) "Source changer" means a device designed and used for replacement of sealed sources in radiographic exposure devices, including those also used for transporting and storage of sealed sources;

(h) "Permanent radiographic installation" means a shielded installation or structure designed or intended for radiography and in which radiography is regularly performed.

44 FR 50805

§ 34.3 Applications for specific licenses.

A person may file an application for specific license for use of sealed sources in radiography in duplicate on NRC Form 313, "Application for Material License," in accordance with the provisions of § 30.32 of this chapter.

49 FR 27923

§ 34.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). OMB has approved the information collection requirements contained in this part under control number 3150–0007.

(b) The approved information collection requirements contained in this part appear in §§ 34.11, 34.24, 34.25, 34.26, 34.27, 34.28, 34.29, 34.31, 34.32, 34.33, and 34.43.

49 FR 19623

49 FR 19623

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In § 34.3, Form NRC-313R is approved under control number 3150-0023.

30 FR 8185

Subpart A—Specific Licensing Requirements

§ 34.11 Issuance of specific licenses for use of sealed sources in radiography.

An application for a specific license for use of sealed sources in radiography will be approved if:

(a) The applicant satisfies the general requirements specified in §30.33 of this chapter;

(b) The applicant will have an adequate program for training radiographers and radiographers' assistants and submits to the Commission a schedule or description of such program which specifies the:

(1) Initial training;

(2) Periodic training;

(3) On-the-job training;

(4) Means to be used by the licensee to determine the radiographer's knowledge and understanding of and ability to comply with Commission regulations and licensing requirements, and the operating and emergency procedures of the applicant; and

(5) Means to be used by the licensee to determine the radiographer's assistant's knowledge and understanding of and ability to comply with the operating and emergency procedures of the applicant;

(c) The applicant has established and submits to the Commission satisfactory written operating and emergency procedures as described in §34.32;

44 FR 50805

(d) The applicant will have an internal inspection system adequate to assure that Commission regulations, Commission license provisions, and the applicant's operating and emergency procedures are followed by radiographers and radiographers' assistants; the inspection system shall include the performance of internal inspections at intervals not to exceed three months and the retention of records of such inspections for two years;

30 FR 8185

(e) The applicant submits a description of its over-all organizational structure pertaining to the radiography program, including specified delegations of authority and responsibility for operation of the program; and

(f) The applicant who desires to conduct his own leak tests has established adequate procedures to be followed in leak testing sealed sources, for possible leakage and contamination and submits to the Commission a description of such procedures including:

(1) Instrumentation to be used,

(2) Method of performing test, e.g., points on equipment to be smeared and method of taking smear, and

(3) Pertinent experience of the person who will perform the test.

Subpart B—Radiation Safety Requirements

EQUIPMENT CONTROL

§ 34.21 Limits on levels of radiation for radiographic exposure devices and storage containers.

Radiographic exposure devices measuring less than four (4) inches from the sealed source storage position to any exterior surface of the device shall have no radiation level in excess of 50 milliroentgens per hour at six (6) inches from any exterior surface of the device. Radiographic exposure devices measuring a minimum of four (4) inches from the sealed source storage position to any exterior surface of the device, and all storage containers for sealed sources or for radiographic exposure devices, shall have no radiation level in excess of 200 milliroentgens per hour at any exterior surface, and ten (10) milliroentgens per hour at one meter from any exterior surface. The radiation levels specified are with the sealed source in the shielded (i.e., "off") position.

44 FR 50805

§ 34.22 Locking of radiographic exposure devices, storage containers, and source changers.

(a) Each radiographic exposure device shall have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. The exposure device or its container shall be kept locked when not under the direct surveillance of a radiographer or a radiographer's assistant or as otherwise may be authorized in § 34.41. In addition, during radiographic operations the sealed source assembly shall be secured in the shielded position each time the source is returned to that position.

(b) Each sealed source storage container and source changer shall have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. Storage containers and source changers shall be kept locked when containing sealed sources except when under the direct surveillance of a radiographer or a radiographer's assistant.

§ 34.23 Storage precautions.

Locked radiographic exposure devices and storage containers shall be physically secured to prevent tampering or removal by unauthorized personnel.

§ 34.24 Radiation survey instruments.

The licensee shall maintain sufficient calibrated and operable radiation survey instruments to make physical radiation surveys as required by this part and Part 20 of this chapter.

41 FR 18300

Each radiation survey instrument shall be calibrated at intervals not to exceed three months and after each instrument servicing and a record shall be maintained of the results of each instrument calibration and date thereof for two years after the date of calibration.

Instrumentation required by this section shall have a range such that two milliroentgens per hour through one roentgen per hour can be measured.

30 FR 8185

§ 34.25 Leak testing, repair, tagging, opening, modification and replacement of sealed sources.

(a) The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing, repair, tagging, opening or any other modification of any sealed source shall be performed only by persons specifically authorized by the Commission to do so.

(b) Each sealed source shall be tested for leakage at intervals not to exceed 6 months. In the absence of a certificate from a transferor that a test has been made within the 6 months prior to the transfer, the sealed source shall not be put into use until tested.

30 FR 8185

(c) The leak test shall be capable of detecting the presence of 0.005 microcurie of removable contamination on the sealed source. An acceptable leak test for sealed sources in the possession of a radiography licensee would be to test at the nearest accessible point to the sealed source storage position, or other appropriate measuring point, by a procedure to be approved pursuant to §34.11(f).

41 FR 18300

Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission for six months after the next required leak test is performed or until the sealed source is transferred or disposed of.

30 FR 8185

(d) Any test conducted pursuant to paragraphs (b) and (c) of this section which reveals the presence of 0.005 microcurie or more of removable radioactive material shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall cause it to be decontaminated and repaired or to be disposed of, in accordance with Commission regulations. A report shall be filed, within 5 days of the test, with the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, describing the equipment involved, the test results, and the corrective action taken. A copy of such report shall be sent to the Director of the appropriate Nuclear Regulatory Commission's Inspection and Enforcement Regional Office listed in Appendix D of Part 20 of this chapter "Standards for Protection Against Radiation."

(e) A sealed source which is not fastened to or contained in a radiographic exposure device shall have permanently attached to it a durable tag at least one (1) inch square bearing the prescribed radiation caution symbol in conventional colors, magenta or purple on a yellow background, and at least the instructions: "Danger–Radioactive Material–Do Not Handle–Notify Civil Authorities if Found."

41 FR 18300

§ 34.26 Quarterly inventory.

Each licensee shall conduct a quarterly physical inventory to account for all sealed sources received and possessed under his license. The records of the inventories shall be maintained for two years from the date of the inventory for inspection by the Commission, and shall include the quantities and kinds of byproduct material, location of sealed sources, and the date of the inventory.

§ 34.27 Utilization logs.

Each licensee shall maintain current logs, which shall be kept available for two years from the date of the recorded event, for inspection by the Commission, at the address specified in the license, showing for each sealed source the following information:

30 FR 8185

(a) A description (or make and model number) of the radiographic exposure device or storage container in which the sealed source is located;

(b) The identity of the radiographer to whom assigned; and

(c) The plant or site where used and dates of use.

44 FR 50805

§ 34.28 Inspection and maintenance of radiographic exposure devices, storage containers, and source changers.

(a) The licensee shall check for obvious defects in radiographic exposure devices, storage containers, and source changers prior to use each day the equipment is used.

(b) The licensee shall conduct a program for inspection and maintenance of radiographic exposure devices, storage containers, and source changers at intervals not to exceed three months or prior to the first use thereafter to assure proper functioning of components important to safety. Records of these inspections and maintenance shall be kept for two years.

§ 34.29 Permanent radiographic installations.

(a) Permanent radiographic installations having high radiation area entrance controls of the types described in § 20.203(c) (2)(ii), (2)(iii), or (4) shall also meet the following special requirement.

(b) Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation to which this section applies shall have both visible and audible warning signals to warn of the presence of radiation. The visible signal shall be actuated by radiation whenever the source is exposed. The audible signal shall be actuated when an attempt is made to enter the installation while the source is exposed.

(c) The alarm system shall be tested at intervals not to exceed three months or prior to the first use thereafter of the source in the installation. Records of the tests shall be kept for two years.

44 FR 50805

PERSONAL RADIATION SAFETY REQUIREMENTS FOR RADIOGRAPHERS AND RADIOGRAPHERS' ASSISTANTS

§ 34.31 Training.

(a) The licensee shall not permit any individual to act as a radiographer until such individual:

(1) Has been instructed in the subjects outlined in Appendix A of this part;

(2) Has received copies of and instruction in NRC regulations contained in this part and in the applicable sections of Parts 19 and 20 of this chapter, NRC license(s) under which the radiographer will perform radiography, and the licensee's operating and emergency procedures;

(3) Has demonstrated competence to use the licensee's radiographic exposure devices, sealed sources, related handling tools, and survey instruments; and

(4) Has demonstrated understanding of the instructions in this paragraph (a) by successful completion of a written test and a field examination on the subjects covered.

(b) The licensee shall not permit any individual to act as a radiographer's assistant until such individual:

(1) Has received copies of and instruction in the licensee's operating and emergency procedures;

(2) Has demonstrated competence to use, under the personal supervision of the radiographer, the radiographic exposure devices, sealed sources, related handling tools, and radiation survey instruments that the assistant will use; and

(3) Has demonstrated understanding of the instructions in this paragraph (b) by successfully completing a written or oral test and a field examination on the subjects covered.

(c) Records of the above training, including copies of written tests and dates of oral tests and field examinations, shall be maintained for three years.

§ 34.32 Operating and emergency procedures.

The licensee's operating and emergency procedures shall include instructions in at least the following:

(a) The handling and use of licensed sealed sources and radiographic exposure devices to be employed such that no person is likely to be exposed to radiation doses in excess of the limits established in Part 20 of this chapter "Standards for Protection Against Radiation";

(b) Methods and occasions for conducting radiation surveys;

(c) Methods for controlling access to radiographic areas;

(d) Methods and occasions for locking and securing radiographic exposure devices, storage containers and sealed sources;

(e) Personnel monitoring and the use of personnel monitoring equipment;

(f) Transporting sealed sources to field locations, including packing of radiographic exposure devices and storage containers in the vehicles, posting of vehicles and control of the sealed sources during transportation;

41 FR 18645

(g) Minimizing exposure of persons in the event of an accident;

(h) The procedure for notifying proper persons in the event of an accident; and

(i) Maintenance of records.

30 FR 8185

(j) The inspection and maintenance of radiographic exposure devices and storage containers.

35 FR 17397

(k) Steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale.

44 FR 50805

(l) The procedure(s) for identifying and reporting defects and noncompliance, as required by Part 21 of this chapter.

42 FR 28891

§ 34.33 Personnel monitoring.

(a) The licensee shall not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each such individual wears a direct reading pocket dosimeter and either a film badge or a thermoluminescent dosimeter (TLD). Pocket dosimeters shall have a range from zero to at least 200 milliroentgens and shall be recharged at the start of each shift. Each film badge and TLD shall be assigned to and worn by only one individual.

(b) Pocket dosimeters shall be read and exposures recorded daily.

(c) Pocket dosimeters shall be checked at periods not to exceed one year for correct response to radiation. Acceptable dosimeters shall read within plus or minus 30 percent of the true radiation exposure.

(d) If an individual's pocket dosimeter is discharged beyond its range, his film badge or TLD shall be immediately sent for processing.

44 FR 50805

(e) Reports received from the film badge or TLD processor shall be kept for inspection until the Commission authorizes their disposal. Records of daily pocket dosimeter readings shall be kept for two years.

46 FR 11804

PRECAUTIONARY PROCEDURES IN RADIOGRAPHIC OPERATIONS

§ 34.41 Security.

During each radiographic operation the radiographer or radiographer's assistant shall maintain a direct surveillance of the operation to protect against unauthorized entry into a high radiation area, as defined in Part 20 of this chapter, except (a) where the high radiation area is equipped with a control device or an alarm system as described in §20.203(c)(2) of this chapter, or (b) where the high radiation area is locked to protect against unauthorized or accidental entry.

§ 34.42 Posting.

Notwithstanding any provisions in §20.204(c) of this chapter, areas in which radiography is being performed shall be conspicuously posted as required by §20.203(b) and (c)(1) of this chapter.

30 FR 8185

§ 34.43 Radiation surveys.

(a) At least one calibrated and operable radiation survey instrument shall be available at the location of radiographic operations whenever radiographic operations are being performed.

(b) A survey with a radiation survey instrument shall be made after each radiographic exposure to determine that the sealed source has been returned to its shielded position. The entire circumference of the radiographic exposure device shall be surveyed. If the radiographic exposure device has a source guide tube, the survey shall include the guide tube.

(c) A record of the survey required in paragraph (b) shall be maintained for two years when the survey is the last survey prior to locking the radiographic exposure device and ending direct surveillance of the operation.

44 FR 50805

§ 34.44 Supervision of radiographers' assistants.

Whenever a radiographer's assistant uses radiographic exposure devices, uses sealed sources or related source handling tools, or conducts radiation surveys required by § 34.43(b) to determine that the sealed source has returned to the shielded position after an exposure, he shall be under the personal supervision of a radiographer. The personal supervision shall include (a) the radiographer's personal presence at the site where the sealed sources are being used, (b) the ability of the radiographer to give immediate assistance if required, and (c) the radiographer's watching the assistant's performance of the operations referred to in this section.

44 FR 50805

EXEMPTIONS

§ 34.51 Applications for exemptions.

The Commission may, upon application by any licensee or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not result in undue hazard to life or property.

49 FR 19623

Appendix A

I. Fundamentals of Radiation Safety

A. Characteristics of gamma radiation.
B. Units of radiation dose (mrem) and quantity of radioactivity (curie).
C. Hazards of exposure to radiation.
D. Levels of radiation from licensed material.
E. Methods of controlling radiation dose:
  1. Working time.
  2. Working distances.
  3. Shielding.

II. Radiation Detection Instrumentation To Be Used

A. Use of radiation survey instruments:
  1. Operation.
  2. Calibration.
  3. Limitations.
B. Survey techniques.
C. Use of personnel monitoring equipment:
  1. Film badges and thermoluminescent dosimeters (TLD's).
  2. Pocket dosimeters.

III. Radiographic Equipment To Be Used

A. Remote handling equipment.
B. Radiographic exposure devices.
C. Storage containers.

IV. Inspection and Maintenance Performed by the Radiographers

V. Case Histories of Radiography Accidents

44 FR 50805

[Note removed 49 FR 19623]

UNITED STATES NUCLEAR REGULATORY COMMISSION

RULES and REGULATIONS

TITLE 10, CHAPTER 1, CODE OF FEDERAL REGULATIONS—ENERGY

PART 34

LICENSES FOR RADIOGRAPHY AND RADIATION SAFETY REQUIREMENTS FOR RADIOGRAPHIC OPERATIONS

PROPOSED RULE MAKING

47 FR 19152
Published 5/4/82

Comment period expires 9/3/82. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

10 CFR Part 34

Certification of Industrial Radiographers

AGENCY: Nuclear Regulatory Commission.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: In this advance notice of proposed rulemaking, the Commission is presenting an alternative to the present system of permitting a radiography licensee to train and designate individuals as radiographers. The suggested alternative would require that each individual who uses byproduct material in industrial radiography be certified by a third party approved by the NRC. This action is intended to ensure that all radiographers possess adequate training and experience to operate radiographic equipment safely. This action is taken in response to a petition for rulemaking and continuing Commission concern over the problem of radiography overexposures.

DATES: Comment period expires September 3, 1982. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

ADDRESSES: Send comments or suggestions to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch. Copies of comments received may be examined at the Commission's Public Document Room at 1717 H Street NW., Washington, D.C. Submit comments in writing or present comments orally at public meetings to be conducted in NRC Regions II, III, IV, V, and in Washington, D.C. in May or June 1982. The exact location, date, and time for each public meeting will be announced at a later date.

FOR FURTHER INFORMATION CONTACT: Mr. James A. Jones, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, 301–443–5970.

SUPPLEMENTARY INFORMATION: Industrial radiography involves the use of relatively large (multicurie) gamma-emitting sealed sources in non-destructive testing of metallic material for defects. Most radiographic operations require use of the sources in open air outside a shielded container. Therefore, a high radiation field is allowed to exist in the areas surrounding the source. NRC licensees must train radiographers to employ sound radiation safety practices to assure that neither the radiographer nor members of the general public are exposed to excessive radiation during the conduct of industrial radiography. The most critical element in the conduct of industrial radiography is for the radiographer to return the source to its shielded container after each radiographic exposure and to verify that the source is in its shielded position.

During the years of 1971 through 1980, radiography licensees, although they constitute approximately 3 percent of NRC material licensees, have been involved in over 60 percent of those reported over-exposures to the whole body that were greater than 5 rems and over 80 percent of whole body exposures greater than 25 rems. The NRC Agreement States have had a similar experience.

Investigations of radiography overexposure incidents have indicated that the majority of the overexposures are the result of a failure by the radiographer to follow established operating procedures. The most common procedure violated is the failure to perform a physical radiation survey after each exposure to verify that the source has been returned to its safe storage position.

Investigations of overexposure incidents by NRC and Agreement State inspectors have also indicated that inadequate training of radiographers may be a significant contributing cause in many of the overexposure incidents. The NRC does not at the present time have an effective means of determining the competency of individual radiographers. The NRC's Office of Inspection and Enforcement, as part of its inspection of radiography licensees, determines the training and knowledge of only a small percentage of the total number of radiographers. Therefore, the training and knowledge of the majority of the individuals conducting radiography in areas under NRC jurisdiction is not known. The lack of an effective means of verifying the training of radiographers by the NRC increases the chance of having inadequately trained individuals using potentially lethal sources of radiation in the public domain.

Under present NRC regulations, individual radiography licensees are permitted under the authority of their licenses to train and designate individuals as qualified to act as radiographers. In such cases, the prospective radiography licensee submits a description of the training program for qualifying individuals to act as radiographers as a part of the overall application for a radiography license. The training program is reviewed for its adequacy by the NRC staff and, if it is found to be acceptable, the licensee is granted authority to train and designate individuals as radiographers. The inherent problem with the present system is the difficulty of verifying the effectiveness of the training programs.

The NRC inspectors' primary means of determining the adequacy of a licensee's training program is by inspecting training records. While training records may serve as evidence that training was given, they do not provide an adequate basis for concluding that the training was effective or that individual radiographers are knowledgeable in NRC regulations and the licensee's operating and emergency procedure.

The Nondestructive Testing Management Association (NDTMA) requested, in a 1977 petition for rulemaking, that the NRC amend its regulations to provide for registration, licensing and control of individual radiographers. This advance notice of proposed rulemaking is being published to resolve the NDTMA petition and to further NRC efforts to improve radiation safety in the radiography industry. In August 1978, the NDTMA petition was published for comment in the **Federal Register** (43 FR 34563). Eleven comments were received concerning the petition. The majority of the comments received concerning the petition stated that the present system for designating individuals as radiographers is adequate and that an NRC licensing program would be costly and would not reduce the number of overexposures in the radiography industry.

In the petition for rulemaking the NDTMA stated that in its opinion the Commission was overlooking a major contributing cause of incidents in the radiography industry. The reference was to cases where the radiographer acts negligently on his own despite being provided proper training, testing, and safety equipment. The NDTMA indicated that a program for licensing and control of individual radiographers would reduce the rate of occurrence of this kind of incident by making individual radiographers more responsible for their actions. The NDTMA added that, "it is not the intent, nor would this proposal in any way reduce the responsibility of the licensee."

The NDTMA petition did not include any information to support its opinion that a national licensing program would motivate individual radiographers to work more safely. Interested persons are specifically invited to comment concerning the motivational aspects of a certification program.

The issue of radiographer licensing has been considered for implementation at various times by the AEC/NRC since 1964. In its past considerations, the staff has not conclusively determined whether an NRC program for licensing of radiographers is desirable. The NRC now believes that due to budgetary constraints and the lack of personnel and equipment, an NEC program for licensing of radiographers is not feasible. However, the NRC does believe that the present system of permitting individual radiography licensees to train and designate individuals as qualified to act as radiographers has deficiencies. An alternative to the present system is discussed below.

Third-Party Certification

The present system for training radiographers permits wide disparity in the competence of individual radiographers depending primarily upon the quality of the particular licensee's training program. The NRC believes the present system would be improved if the final determination of competence to act as a radiographer was made by an independent body. In view of the limited staff resources, the NRC believes the development of a regulatory program that incorporates a third-party certification requirement for individual radiographers is the most feasible means of increasing NRC's assurance of the competency of radiographers. The NRC would encourage and support initiatives on the part of the radiography industry in establishing a third-party certification program for testing radiographers.

Implementation of a third-party certification program would require the development of a certification standard that is satisfactory to the NRC, the radiography industry, and other interested persons. The NRC would also be required to amend 10 CFR Part 34 of its regulations to specify that only individuals who have been tested and certified as meeting the provisions of the standard may act as radiographers under the authority of NRC licensees.

The NRC would especially appreciate receiving comments from organizations that would be interested in participating in a third-party certification program for industrial radiographers. Participants in the program could be either organizations that promote the nondestructive testing industry or organizations that are independent from the industry. The NRC would make a determination as to whether to recognize a particular organization's program for certification. Following acceptance of an organization's certification program as meeting NRC standards, the NRC regulations would be amended to require certification by that organization.

Radiography-Licensee Designation (Status Quo)

An alternative to the third-party certification program would be to continue with the present system of permitting radiography licensees to train and designate their own radiographers.

Invitation To Comment

Comments concerning the desirability of establishing a third-party certification program for certifying radiographers are invited. Comments are specifically solicited concerning the alternatives described in this notice. Suggestions of other alternatives, and estimates of costs for implementation of the programs, are encouraged.

In light of previous discussion, the NRC is particularly interested in receiving comments concerning the following:

1. Is the training provided to radiographers under the present system adequate?
2. Would a third-party certification program reduce the number of overexposures in the radiography industry?
3. Would a third-party certification program motivate radiographers to work more safely?
4. What elements in the present system or in the suggested alternative are particularly desirable or undesirable? Why?
5. If a third-party certification program is adopted, what items should be included in the standard for determining the competence of individuals to act as radiographers?
6. If a third-party certification program is adopted, should it apply to individuals presently working as radiographers or only to new radiographers?
7. If a third-party certification program is adopted, should certificates be issued to individuals for life or should there be periodic renewals of the certification?
8. Would a third-party certification program affect the ability of a licensee to respond to variable manpower needs?
9. Since a third-party certification

program would likely to be based on cost recovery by a fee system, would the cost to the licensees of such a program be warranted?

10. Which alternatives of the two discussed (present system, third-party certification) is preferable? Why? Are there other better alternatives? If so, please explain.

11. With respect to the two alternatives, what kind of enforcement action could and should be taken against radiographers who do not operate equipment safely or follow established procedures? What rights should radiographers have with respect to such enforcement actions?

12. Would a small licensee, because of its size bear a disproportionate adverse economic impact under a third-party system?

13. For those organizations that are interested in participating in a third-party certification program, what would be the estimated cost in implementing such a program?

List of Subjects in 10 CFR Part 34

Packaging and containers, Penalty, Radiation protection, Radiography, Reporting requirements, Scientific equipment, Security measures.

(Sec. 161, Pub. L. 83-703, 68 Stat. 948, as amended (42 U.S.C. 2201))

Dated at Washington, DC this 27th day of April 1982.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

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49 FR 39168
Published 10/4/84

10 CFR Part 34

Industrial Radiography Radiation Surveys and Licensee's Performance Inspection Program

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission is proposing to amend its regulations that apply to industrial radiography. The proposed rule would require industrial radiography licensees to perform an additional survey of any radiography device at any time the device is put into storage, and would change an existing recordkeeping requirement. Currently, each licensee must record the required survey of the device made after the last exposure before storage. The proposed rule deletes this recordkeeping requirement and substitutes a requirement that a record of the new storage survey be maintained. The proposed rule would also require that each license application describe the program the licensee will use to evaluate the performance of each radiographer and radiographer's assistant at intervals not exceeding 3 months to ensure that they are following the Commission's regulatory requirements and the licensee's operating and emergency procedures when performing radiography. This action is intended to provide additional assurance that radiographic operations are conducted safely.

DATE: Submit comments by November 18, 1984. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

ADDRESSES: Send comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, ATTN: Docketing and Service Branch. Hand deliver comments to: Room 1121, 1717 H Street NW., Washington, DC, between 8:15 a.m. and 5:00 p.m. Examine comments received and the regulatory analysis at: NRC Public Document Room, 1717 H Street NW., Washington, DC. Obtain regulatory analysis (single copy) from: Donald O. Nellis, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 427-4588.

FOR FURTHER INFORMATION CONTACT: Donald O. Nellis, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 427-4588.

SUPPLEMENTARY INFORMATION: The Nuclear Regulatory Commission is considering three amendments to its regulations pertaining to industrial radiography. One amendment would require licensees to perform an additional radiation survey of the radiographic exposure device at the time of storage, delete an existing requirement to record the radiation survey made of the device immediately after the last exposure prior to storage, and add a requirement to make and maintain a record of the storage survey. This amendment to § 34.43 would provide a method of ensuring that the sealed source is in the proper position within the device when the device is stored. The second amendment would revise § 34.11(d) to specify that each license application must describe a program by which the licensee will evaluate the performance of each radiographer and radiographer's assistant at intervals not exceeding 3 months. This amendment would clarify the requirements for the description of the in-house inspection program that the applicant must provide in the license application. The third amendment provides a definition of "storage area" in § 34.2, *"Definitions"*. This definition is provided so that it is clear at what locations the storage survey is to be made. Interested persons are invited to comment on any or all of the proposed amendments.

Radiation Survey and Record

The Commission received a petition for rulemaking, assigned Docket No. PRM-34-3, from the Chicago Bridge and Iron Company. The Commission requested comments on the petition in the **Federal Register** on November 23, 1982 (47 FR 52722). As discussed below, this proposed rule would in effect grant the petition. The petitioner suggested an amendment of 10 CFR 34.43(c) that would require that each licensee survey a radiographic exposure device when it is placed in storage. This survey would be made using a radiation survey instrument at a point on the surface of the device specified by the licensee in its operating procedures. This last survey would occur at or near the place of storage, and would provide a record showing that the radiographic exposure device had been stored with the sealed source in a safe location within the device.

Under the current regulations, § 34.43(b) requires that, after each radiographic exposure, the radiographer perform a radiation survey of the radiographic device to ensure that the sealed source has been returned to its shielded position. Paragraph (c) of § 34.43 requires that the radiographer record the results of the survey following the last radiographic exposure made before locking the device and ending direct surveillance of the operation. This survey is made where the device is last used before storage. The licensee must keep a record of the survey for 2 years.

The petitioner contends that because no check of the sealed source position is required, the current regulation does not ensure safe storage of the sealed source in the radiographic device, yields equivocal records, and is inconvenient. More specifically, the petitioner contends that the device may be subject to rough handling when being moved under field conditions from the area of use to the area of storage. If the source were dislodged during the movement to the storage area, the radiographer might store the device with the sealed source outside of its proper location within the device. The petitioner contends that, by requiring that the radiographer make the final survey at the time of storage and at a point on the device specified by the licensee in its operating procedures, the recorded exposure rate would provide unequivocal assurance that the source was properly located within the device, and would also provide a check on the decay of the sealed source and the constancy of the survey instrument. The petitioner also contends that it is easier to record the survey data at the location of storage than at the location of use because of weather and work conditions that are encountered in field radiography.

The Commission received one telephone and three written comments on the petition. Three commenters concurred completely with the petition. One commenter said that the survey should be made at the sealed source outlet port with the safety plug installed. One commenter said that licensees should not be required to submit modified procedures for review until it was time for them to renew their licenses.

The petitioner's suggested amendment would eliminate the requirement that the last-use survey be recorded, and put in its place a requirement that a time-of-storage survey be made and recorded. Although the Commission is aware of only one overexposure that was caused by failure of the locking mechanism (NUREG/BR-0024, p. 153, case 46 [1]) followed by moving the radiographic device, several incidents have been observed where radiographic devices were stored with the source in an unshielded position caused by failure to lock the mechanism. The probability of occurrence and the consequences of this type of event seem to be of sufficient magnitude to justify the time-of-storage survey requirement suggested by the petitioner. In addition it is considered to be a good safety practice to survey at the time of storage, and many radiographers include this survey in their routine procedures. Therefore, the Commission agrees that it is desirable to require that the time-of-storage survey be made and recorded. However, this would not relieve licensees from requiring that radiographers make a survey immediately after the last exposure and before transport to the place of storage, although no record of the last use survey would be required.

The Commission also agrees that the measurement of the exposure rate at a point on the surface of a device, during the storage survey, would provide additional assurance that the sealed source was properly stored within the device as well as data on source decay and instrument operability useful to both the licensee and NRC inspectors. However, storage survey procedures should also be consistent with the survey procedure required after each exposure. Therefore, the proposed amendment would require that the time-of-storage survey be made around the entire circumference of the radiographic exposure device, consistent with existing survey procedures (10 CFR 234.43(b)), and that the survey include a measurement of the radiation exposure rate at the source outlet port with the safety plug installed, as recommended by one commenter.

A record of the time-of-storage survey result would provide assurance to the Commission that the radiographer had surveyed the device after the last exposure. The Commission agrees that it may be more convenient to record the results of a survey taken at the location of storage than one taken in the field, and that this storage survey record may be more important to safety.

Since the time-of-storage survey and record procedure are similar to the currently required last-use survey and record procedure, licensees would not be required to submit modified procedures for review. If the Commission implements the proposed rule, a copy will be sent to each licensee. A cover letter will inform the licensee that the new survey and record method should be used and that a license amendment need not be requested.

Performance Inspection of Radiographers and Radiographers' Assistants

In order to receive a specific license for radiography, the applicant presently must have an in-house inspection program to ensure that radiographers and radiographer's assistants are following NRC regulatory requirements and the licensee's operating and emergency procedures. The in-house inspection must be conducted by the licensee every 3 months. This requirement was intended to be explicit in § 34.11(d) of the Commission's rules.

The Commission intends that the applicant describe in the license application the program that will be used to inspect the work methods of each radiographer and radiographer's assistant during an actual radiographic operation to ensure that each individual is following applicable regulatory requirements and operating and emergency procedures. Each inspection would be conducted by having an individual who knows the applicable requirements and procedures observe each worker during an actual radiographic exposure to ensure that each worker is following the requirements and procedures. The proposed rule clarifies this requirement. Some license applicants and licensees believe that a system of spot checks of some radiographers and radiographers' assistants is sufficient to meet the requirement of existing regulation. The Commission does not agree that a system of spot checks is adequate to provide assurance that radiographers are working safely. The Commission is proposing that the regulation be revised to specify that a description of the inspection program be included in license applications and that the inspection program provide for the inspection of the work methods of each radiographer and radiographer's assistant actively engaged in radiography, at intervals not to exceed 3 months. If a radiographer has not participated in a radiographic operation for more than three months, the rule provides that individual's performance will be observed and recorded the next time he or she participates in a radiographic operation.

Environmental Impact: Categorical Exclusion

The NRC has determined that this proposed regulation is the type of action described in categorical exclusion 10 CFR 51.22(c)(3) (i) and (iii). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this proposed regulation.

Paperwork Reduction Act Statement

This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act (44 U.S.C. 3051 et seq.). This rule has been submitted to the Office of Management and Budget for review and approval of the paperwork requirements as part of the 1983 renewal for 10 CFR Part 34. Approval of the paperwork requirement was granted 08/10/83, OMB No. 3150-0007.

Regulatory Analysis

The Commission has prepared a regulatory analysis on this proposed regulation. This analysis examines the costs and benefits of the alternatives considered. The analysis is available for inspection in the Public Document Room, 1717 H Street NW., Washington, DC. Single copies of the analysis may be obtained from Donald O. Nellis, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 427-4588.

Public comment on the analysis is requested. Comments may be submitted to the NRC as indicated under the

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[1] Copies of NUREG/BR-0024 may be obtained from the GPO Sales Program Division of Technical Information and Document Control. U.S. Nuclear Regulatory Commission. Washington. DC 20555. telephone (301) 492-7333.

ADDRESSES heading.

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this rule, if adopted, will not have a significant economic impact on a substantial number of small entities. The NRC has currently issued 369 licenses for the performance of industrial radiography, that would be affected by this proposed rule. Although a substantial number of these licensees would be considered small entities, the proposed requirements are not expected to have a significant economic impact on these licensees.

The proposed radiation survey and record amendment requires an additional survey upon storage of the radiographic device, which is considered a minimal regulatory burden. The amendment substitutes a storage survey record requirement for the currently required last use survey record, which imposes no additional regulatory burden. The quarterly performance inspection of each radiographer and radiographer's assistant is already required of license applicants. The proposed rule clarifies what information must be submitted with a license application.

The additional time-of-storage survey is estimated to cost about $150.00 per radiographer per year. This is based on each radiographer working 250 days each year, at two locations each day, and estimate that it takes about 0.01 hours to complete a storage survey, and that the hourly wage for the average radiographer, plus overhead, is $30.00. Each survey can be estimated to cost approximately 30 cents. The benefit of this additional survey requirement is significantly increased assurance that radiographic sources are safety stored in the shielded position.

Since the quarterly performance inspection of radiographers is already required by license condition, there will be no new or additonal burden on NRC licensees. The total cost of the quarterly performance inspection program, whether required by license condition or regulation, is about $120 per worker each year, assuming each inspection takes one-half hour of worker time and one-half hour of inspector time.

The NRC does not believe these costs constitute a significant economic impact on small entities. However, the Commission is seeking comments and suggested modifications, especially from small entities, because of the widely differing conditions under which many licensees operate.

Any small entity subject to this regulation which determines that, because of its size, it is likely to bear a disproportionate adverse economic impact should notify the Commission of this in a comment that indicates the following:

(a) The licensee's size in terms of annual income or revenue and number of employees;

(b) How the proposed regulation would result in a significant economic burden upon the licensee as compared to that on a large licensee;

(c) How the proposed regulations could be modified to take into account the licensee's differing needs of capabilities; and

(d) Whether the assumptions that a radiographer works an average of two locations a day and that a radiation survey takes about 0.01 hour to complete accurately reflect the licensees' actual work experience.

List of Subjects in 10 CFR Part 34

Packaging and containers, Penalty, Radiation protection, Radiography, Reporting and recordkeeping requirements, Scientific equipment, Security measures.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C 553, the NRC is proposing to adopt the following amendments to 10 CFR Part 34.

PART 34—LICENSES FOR RADIOGRAPHY AND RADIATION SAFETY REQUIREMENTS FOR RADIOGRAPHIC OPERATIONS

1. The authority citation for Part 34 is revised to read as follows:

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

Section 34.32 also issued under sec. 206, 88 Stat. 1246 (42 U.S.C. 5846).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 34.22, 34.23, 34.24, 34.25 (a), (b) and (d), 34.28, 34.29, 34.31 (a) and (b), 34.32, 23.33 (a), (c) and (d), 34.41, 34.42, 34.43 (a) (b) and (c) and 34.44 are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§ 34.11 (d), 34.25 (c) and (d), 34.26, 34.27, 34.28(b), 34.29(c), 34.31(c), 34.33 (b) and (e) and 34.43(d) are issued under sec. 1610, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

§§ 34.2, 34.11, 34.22, 34.28, 34.29, 34.31–34.33, 34.43–34.44, 34.51 and Appendix A [Amended]

2. Remove the authority citations following §§ 34.2, 34.11, 34.22, 34.28, 34.29, 34.31, 34.32, 34.33, 34.43, 34.44, 34.51, and Appendix A.

3. In § 34.2 paragraphs (g) and (h) are redesignated as paragraphs (h) and (i), and a new paragraph (g) is added to read as follows:

§ 34.2 Definitions.

* * * * *

(g) "Storage area" means any location, facility, or special vehicle at or in which a radiographic exposure device or storage container is secured, when not in use, by lock or physical barrier so as to prevent accidental exposure, tampering with or unauthorized removal of the device.

* * * * *

4. In § 34.11, paragraph (d) is revised to read as follows:

§ 34.11 Issuance of specific licenses for use of sealed sources in radiography.

* * * * *

(d) The applicant has established and submits a description of an in-house inspection program adequate to ensure that the Commission's regulatory requirements and the applicant's operating and emergency procedures are followed by radiographers and radiographers' assistants. The inspection program must:

(1) Include observation of and recording of the performance of each radiographer and radiographer's assistant during an actual radiographic operation at intervals not to exceed three months;

(2) Provide that, if a radiographer and radiographer's assistant has not participated in a radiographic operation for more than three months since the last inspection, that individual's performance must be observed and recorded the next time the individual participates in a radiographic operation; and

(3) Include retention of inspection records for two years on performance of radiographers and radiographer's assistants.

* * * * *

5. Section 34.43 is revised to read as follows:

§ 34.43 Radiation surveys.

(a) The licensee shall ensure that at least one calibrated and operable radiation survey instrument is available at the location of radiographic operations whenever radiographic operations are being performed, and at the storage area as defined in § 34.2(g) whenever a radiographic exposure device is being placed in storage.

(b) The licensee shall ensure that a survey with a calibrated and operable radiation survey instrument is made after each exposure to determine that the sealed source has been returned to its shielded position. The entire circumference of the radiographic exposure device must be surveyed. If the radiographic exposure device has a source guide tube, the survey must include the guide tube.

(c) The licensee shall ensure that a survey with a calibrated and operable radiation survey instrument is made at the time a radiographic exposure device is placed in a storage area to determine that the sealed source is in its shielded position. The entire circumference of the radiographic exposure device must be surveyed. In addition, for devices having a source outlet port, a measurement of the radiation exposure rate at this outlet port, with the safety plug installed, must be taken.

(d) The licensee shall ensure that a record of the survey required in paragraph (c) of this section, including the measurement of the radiation exposure rate at the source outlet port, with the safety plug installed, is made and is maintained for two years.

Dated at Bethesda, Maryland, this 27th day of August, 1984.

For the Nuclear Regulatory Commission.

William J. Dircks,

Executive Director for Operations.

PART 34

LICENSES FOR RADIOGRAPHY AND RADIATION SAFETY REQUIREMENTS FOR RADIOGRAPHIC OPERATIONS

PETITIONS FOR RULE MAKING

43 FR 34563
Published 8/4/78
Comment period expires 10/3/78

[Docket No. PRM-34-2]

NON DESTRUCTIVE TESTING MANAGEMENT ASSOCIATION

Filing of Petition for Rulemaking

Notice is hereby given that Mr. Walter P. Peeples, Jr., President, Non Destructive Testing Management Association, has filed with the Nuclear Regulatory Commission a petition for rulemaking to amend the Commission's regulations.

By letter dated June 24, 1977, Mr. Peeples proposed a system for the registration of industrial radiographers. This proposal has been under review by the NRC staff since that time. On June 28, 1978, Mr. Peeples requested that his letter be considered a petition for rulemaking pursuant to § 2.802 of 10 CFR Part 2 of the Commission's regulations, and it has been so accepted by the Commission.

The petitioner requests the Commission to amend its regulations to provide for registration, licensing, and control of individual radiographers. Attached to the petition is an outline of a suggested program for NRC registration of industrial radiographers. The petitioner states that registration and licensing of individual radiographers would reduce overexposure and prevent needless exposure.

The purpose of the petition is set forth in section 1.0 of the attachment to the petition, as follows:

1.0 PURPOSE

To reduce the incidence of overexposure, to prevent needless exposure, to curtail noncompliance, and advance the overall safety of the radiographic industry.

1.1 DISCUSSION

It is the consensus opinion in the industrial radiographic industry that the Commission is overlooking a major contributing cause of incidents in the industry. The reference is to those cases where the radiographer is acting independently and negligently on his own despite being provided proper training, testing, and adequate safety equipment. It is proposed that only through the registration, licensing, and control of the individual radiographer can the industry overexposure record be improved. the NDTMA is convinced that until the radiographer is motivated by a sense of individual responsibility for his own acts and their results, will the industry be a safer one. It is recommended that the registration program would serve several purposes. First, it would provide the radiographer with a sense of pride in his knowledge that he has been registered by a government body. Secondly, an awareness that he is directly responsible for his safety performance. Third, that he is accountable for his conduct to the extent his registration could be limited, suspended, or revoked and future employment in the industry affected. Fourth, it would provide continuity of safety training and testing in an industry where employment is very mobile. It is not the intent, nor would this proposal in any way reduce the responsibility of the licensee.

A copy of the petition for rulemaking is available for public inspection in the Commission's Public Document Room, 1717 H Street NW., Washington, D.C. A copy of the petition may be obtained by writing to the Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

All persons who desire to submit written comments or suggestions concerning the petition for rulemaking should send their comments to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch by October 3, 1978.

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47 FR 31887
Published 7/23/82

10 CFR Part 34

[Docket No. PRM-34-2]

Withdrawal of Petition for Rulemaking; Nondestructive Testing Management Association

AGENCY: Nuclear Regulatory Commission.

ACTION: Withdrawal of petition for rulemaking.

SUMMARY: In the Federal Register of August 4, 1978 (43 FR 34563), the Commission announced the receipt of and requested comments on a petition for rulemaking (PRM-34-2) filed by the Non-Destructive Testing Management Association. The petition, dated June 28, 1978, requested that the Commission amend its regulations to provide for the registration, licensing, and control of individual radiographers. By letter dated May 10, 1982, the petitioner has withdrawn its petition for rulemaking. The petitioner did not indicate any reason for withdrawing the petition in the letter requesting this action.

The Nuclear Regulatory Commission has been studying the problem of radiography overexposures. As a part of its program to reduce the extent and seriousness of this problem, NRC published on May 4, 1982 (47 FR 19152) an advance notice of proposed rulemaking investigating the possibility of third-party certification of industrial radiographers. Although this ANPRM was issued partially in response to PRM-34-2, the staff intends to continue this rulemaking action because of the continuing concern regarding radiography exposures.

ADDRESSES: A copy of the petitioner's letter of withdrawal is available for public inspection in the Commission's Public Document Room, 1717 H Street, NW., Washington, DC. A copy of the letter of withdrawal may be obtained by writing to the Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

FOR FURTHER INFORMATION CONTACT: John D. Philips, Chief, Rules and Procedures Branch, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: (301) 492-7086 or Toll Free: 800-368-5642.

Dated at Bethesda, Maryland this 13th day of July 1982.

For the Nuclear Regulatory Commission.

William J. Dircks,

Executive Director for Operations.

47 FR 52722
Published 11/23/82

10 CFR Part 34

Receipt of Petition for Rulemaking From the Chicago Bridge and Iron Company

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking.

SUMMARY: The Nuclear Regulatory Commission is publishing for public comment a notice of receipt of a petition for rulemaking submitted by the Chicago Bridge and Iron Company. The petitioner requests that the NRC amend its regulations to require that a radiation survey be made at a point on the surface of a radiographic exposure device when the device is stored following use. The petitioner believes that the amendment is necessary to provide a recorded survey that would determine that the radiographic exposure device is stored with the sealed source in its safe location in the device.

DATE: Submit comments by January 24, 1983. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

ADDRESSES: Submit comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

Hand deliver comments to: Room 1121, 1717 H Street, NW, Washington, DC between 8:15 a.m. and 5:00 p.m.

For a copy of the petition write: The Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

Inspect and copy comments received on the petition at: The NRC Public Document Room, 1717 H Street, NW, Washington, DC.

FOR FURTHER INFORMATION CONTACT: John D. Philips, Chief, Rules and Procedures Branch, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: (301) 492–7086 or call toll free (800) 368–5642.

SUPPLEMENTARY INFORMATION: The Nuclear Regulatory Commission received a petitioin for rulemaking from the Chicago Bridge and Iron Company. This petition has been assigned Docket No. PRM–34–3. The petitioner suggests an amendment to § 34.43(c) that would specify additional requirements for the last survey of a radiographic exposure device that is made after the device has been used. This survey would be made by a radiation survey instrument at a point on the surfaced of the device when the device is stored. This last survey would occur at or near the place of storage. The intent of the petitioner is to provide a recorded survey that would be useful in determining that the radiographic exposure device is stored with the sealed source in a safe location in the device.

Currently, the text of § 34.43(c) reads as follows:

> "(c) A record of the survey required in paragraph (b) shall be maintained for two years when the survey is the last survey prior to locking the radiographic exposure device and ending direct surveillance of the operation."

Paragraph (b) of § 34.43 requires that a survey of the exposure device be made after each exposure period. The petitioner believes that using the last survey as the recorded survey is not a sufficient method of determining that the exposure device is stored with its sealed source in the proper position.

The petitioner believes that a radiation survey of the radiographic exposure device at the time of storage is essential to safe operation. This is not currently required by the regulations in § 34.43(b) and (c). Therefore, the petitioner requests that § 34.43(c) be revised to specify that the last survey be made at the time of storage. In addition, the petitioner would require this survey to be made at a point on the surface of the device and at or near the place of storage The language suggested by the petitioner for the revised § 34.43(c) is as follows:

> "(c) A survey with a radiation survey instrument shall be made at a point on the surface of the radiographic exposure device, specified by the licensee, at or within the storage area when storing. This survey shall be recorded and maintained for two years from the date of the survey."

The petitioner presents the following arguments in support of the suggested amendment.

1. The petitioner asserts that because the exposure device may be subject to rough handling in transferring it from the work area to the storage area, there have been instances where the sealed source was in the radiographic exposure device after the final exposure but outside the device when the device was stored. The petitioner contends that by requiring the final survey at the time and place of storage, a recorded survey would indicate whether the sealed source had been dislodged form its proper place in the exposure device.

2. The petitioner contends that, as currently required by § 34.43 (b) and (c), the reading recorded from the final survey could be between 0 MR and 200 MR, and there would be no assurance that the radiographer had made an accurate reading. By requiring that the survey be made at a specified point on the exposure device, the petitioner believes that the recorded survey becomes more meaningful in that it provides a check on the decay of the sealed source and indicates that the survey instrument is working properly.

3. The petitioner implies that because much radiography is performed off-shift and occasionally under adverse conditions, the currently recorded final survey may not be an accurate record. The petitioner believes that requiring the final survey at the time and place of storage would result in a more accurate record and increased assurance of safe storage.

The Commission would like to receive public comment on the specific items addressed in PRM–34–3. Those who intend to submit comments on the petition may obtain a complete copy of the petition from the Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

Washington, DC, this 17th day of November 1982.

For the Nuclear Regulatory Commission.

John C. Hoyle,
Acting Secretary of the Commission.

UNITED STATES NUCLEAR REGULATORY COMMISSION

RULES and REGULATIONS

TITLE 10, CHAPTER 1, CODE OF FEDERAL REGULATIONS—ENERGY

PART 34

LICENSES FOR RADIOGRAPHY AND RADIATION SAFETY REQUIREMENTS FOR RADIOGRAPHIC OPERATIONS

STATEMENTS OF CONSIDERATION

30 FR 8185
Published 6/26/65
Effective 8/25/65

See Part 30 Statements of Consideration.

35 FR 17397
Published 11/13/70
Effective 12/13/70

Inspection and Maintenance Programs

On June 26, 1970, the Atomic Energy Commission published in the Federal Register (35 F.R. 10461) proposed amendments to its regulation, "Licenses for Radiography and Radiation Safety Requirements for Radiographic Operations", 10 CFR Part 34, to require persons licensed to use byproduct material for radiography to have programs for the inspection and maintenance of radiographic exposure devices and storage containers.

All interested persons were invited to submit written comments and suggestions for consideration in connection with the proposed amendments within sixty (60) days after publication of the notice in the Federal Register. After consideration of the comments and other factors involved, the Commission has adopted the proposed amendments. The text of the amendments set out below is identical to the text of the proposed amendments published June 26, 1970.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 34, are published as a document subject to codification effective thirty (30) days after publication in the Federal Register.

41 FR 18300
Published 5/3/76
Effective 6/2/76

Preservation of Records

See Part 20 Statements of Consideration.

41 FR 18645
Published 5/6/76
Effective 8/4/76

PART 34—LICENSES FOR RADIOGRAPHY AND RADIATION SAFETY REQUIREMENTS FOR RADIOGRAPHIC OPERATIONS

Personnel Monitoring of Radiographers

On October 11, 1974, the Atomic Energy Commission published in the Federal Register (39 FR 36601) a proposed amendment of 10 CFR Part 34 of its regulations. The proposed amendment would have allowed radiographers and their assistants to use either film badges or thermoluminescence dosimeters (TLD's) to record exposures. Existing regulations permitted only the use of film badges. The amendment was thought desirable because the Commission staff believed TLD's to be as effective as film badges and superior to film badges in certain applications.

The amendment also would have required that direct-reading pocket dosimeters be used instead of pocket dosimeters or pocket chambers that require a separate device for reading. It was believed that this change would provide greater safety for radiographers by making it easier for them to check at any time the radiation doses they had received.

On October 11, 1974, the Energy Reorganization Act of 1974 [1] was enacted into law. This Act abolished the Atomic Energy Commission and, by section 201 established the Nuclear Regulatory Commission (NRC) and transferred to that Commission all of the licensing and related regulatory functions of the Atomic Energy Commission. In addition, section 301 of the Energy Reorganization Act provided that any proceedings pending before the AEC at the time of its abolition shall, to the extent that such proceedings relate to functions transferred by the Act, be continued.

All interested persons were invited to submit written comments on the proposed amendment by December 10, 1974. Six public comments on the proposed amendment were received. Four endorsed the amendment, although one of these suggested additional requirements. One comment stated that TLD's should be evaluated more fully before allowing their use, and one comment was opposed to permitting the use of TLD's. The specific comments made are discussed below.

It was suggested that the amendment should not be adopted until a study to compare the accuracy of film and TLD's, being funded by the Bureau of Radiological Health, is completed. The study is now complete. It showed that TLD's can perform comparably with film.[2] A similar study at the National Sanitation Foundation, Ann Arbor, Michigan, had similar results.[3]

It was also suggested that the regulation should specify the types of TLD chips that are considered acceptable. The Commission does not consider such detail desirable for this regulation.

It was further suggested that the competency of each company offering a dosimeter service should be tested. The NRC staff has such a requirement under consideration.

One comment stated that the notice of proposed rule making was in error in stating that TLD's are more sensitive to low doses than film. The two studies mentioned above did seem to indicate that film is more accurate and more sensitive at low doses. Nevertheless, the Commission considers the performance of TLD's at low doses to be acceptable.

The same commenter also noted that TLD's have other disadvantages in comparison to film. Upon reading of a TLD the signal is obliterated so that reader malfunction can cause loss of data. TLD's are inferior in determining the energy of the radiation. TLD's give no information as to the direction of the exposure. TLD's do not provide a "picture" as does film; for example, TLD's do not give an image which indicates if an exposure was received from a single well-defined source, several such sources, or various diffuse sources. While these points are valid, film also has disadvantages. Accidents or errors in processing the film can cause loss of the data. High humidity causes fogging and loss of data. Ripped packages or water soaking cause loss of data. On balance, it does not appear that one system is sufficiently superior to the other to justify restriction by regulation the use of only one: the Commission believes both types of personnel dosimeters are acceptable. Under the provisions of § 20.202, 10 CFR Part 20, all licensees other than radiographers are permitted to use TLD's to record exposures.

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[1] Public Law 93-438 (88 Stat. 1233).

[2] Available from Caleb Kincaid, Bureau of Radiological Health, 1901 Chapman Ave., Rockville, Md. 20852. Copy available for inspection in the NRC Public Document Room, 1717 H Street NW., Washington, D.C.

[3] Available from Gary Sherlaw, National Sanitation Foundation, Ann Arbor, Michigan 48105. Copy available for inspection in the NRC Public Document Room, 1717 H Street NW., Washington, D.C.

According to one comment, audible pocket alarm systems and digital readout dosimeters should be required. The Commission does not consider such systems to be essential and does not intend to require their use at this time. (Electronic digital readout dosimeters are direct reading and may be used to meet the requirements of § 34.33 in place of the more common direct-reading pocket ionization chambers.) The Commission does intend to investigate the desirability of requiring personal audible alarm systems. Persons wishing to comment on the desirability of such a requirement should write to the Occupational Health Standards Branch, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 by August 1, 1976.

It was suggested that the initial and subsequent calibrations of self-reading dosimeters be required. This is already recommended in the staff's Regulatory Guide 8.4, "Direct-reading and Indirect-reading Pocket Dosimeters."

An upper limit on the range of self-reading dosimeters was suggested so that a dosimeter with too coarse a scale would not be used. The Commission does not consider this to be necessary. Experience has shown that licensees have used good judgment in this regard.

Another comment suggested that if an individual's dosimeter were discharged beyond its range, that individual should be prohibited from further radiation work during that quarter until the film badge could be processed. This problem is already covered in the Commission's regulations. If a licensee believes an individual may be overexposed, it is already the licensee's responsibility under § 20.101 to prevent further exposure during that quarter.

After careful consideration of the comments received, and other factors involved, the Commission has adopted the amendment set forth below. The only difference from the amendment published for comment is the addition of a requirement that licensees maintain certain reports and records related to the dosimeters until the Commission authorizes their disposal. The proposed rule did not specifically state the conditions under which a licensee could dispose of such records or reports.

In accordance with the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendment of Title 10, Chapter I, Code of Federal Regulations, Part 34 is published as a document subject to codification.

42 FR 28891
Published 6/6/77
Effective 7/6/77; §§21.6, 21.21(a), and 21.51 effective 1/6/78
(7/6/77 effective date extended to 8/10/77)

Reports to the Commission Concerning Defects and Noncompliance

See Part 21 Statements of Consideration.

44 FR 50805
Published 8/30/79
Effective 3/3/80

10 CFR Part 34

Licenses for Radiography and Radiography Safety Requirements for Radiographic Operations; Amendments of Radiography Regulations

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is publishing as effective rules several changes in its regulations on industrial radiography. The rule changes were originally published for public comment on March 27, 1978, and have been revised after consideration of the comments received. These amendments require several procedural changes intended to improve radiography safety. The changes are also intended to formalize as regulations current licensing practices. The amendments apply to industrial radiography operations using radioactive isotope sources licensed by the Nuclear Regulatory Commission.

EFFECTIVE DATE: March 3, 1980.

Note.—The Nuclear Regulatory Commission has submitted this rule to the Comptroller General for such reviews as may be appropriate under the Federal Reports Act, as amended, 44 U.S.C. 3512. The date on which the reporting requirement of this rule becomes effective, unless advised to the contrary, accordingly reflects inclusion of the 45-day period which that statute allows for such review (44 U.S.C. 3512(c)(2)).

FOR FURTHER INFORMATION CONTACT: Dr. Stephen A. McGuire, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, (301) 443-5970.

SUPPLEMENTARY INFORMATION: On March 27, 1978, the Nuclear Regulatory Commission published for public comment amendments to Part 34 of its regulations (43 FR 12715). Forty-nine public comments were received. In response to these comments, some of the proposed amendments have been deleted or substantially reworded. The individual amendments are discussed by section below.

§ *34.2 [Amended].*

New definitions for "source changer," now used in § 34.22 and § 34.28 and "permanent radiographic installation," now used in § 34.29, are given.

§ *34.11(d) [Amended].*

The proposed amendment specified that internal inspections would be required at intervals not to exceed three months. The predominant comment was that this frequency was too restrictive. The NRC believes the proposed frequency is appropriate in view of the importance of management audits of radiographer performance. The NRC has consistently observed that a strong management commitment to safety is necessary if radiographic operations are to be conducted safely. Frequent checks of the performance of radiographers are a necessary part of that commitment. The effective rule therefore retains the proposed frequency for internal inspections.

§ *34.22 [Amended].*

The proposed amendment specified securing (not necessarily locking) the sealed source in its shielded position in crankout radiographic exposure devices each time the source is returned to that position. Some commenters questioned the effectiveness of such a requirement. Other commenters thought the requirement should not be limited to crankout devices only. On consideration, the NRC believes the small effort to secure the source is worthwhile since this prevents the source from moving out of its shielded position if the device or the crank is moved. The NRC also has extended the requirement to devices other than crankout devices since the safety considerations with such devices are similar to those for crankout devices.

§ *34.28 [Amended].*

The proposed amendment specified that radiographic exposure devices, storage containers, and source changers be maintained at intervals not to exceed three months. The main comment was that this schedule was too restrictive. The NRC agrees that more flexibility in scheduling can be permitted with little or no loss in effectiveness of the regulation. In response the schedule is changed to "at intervals not to exceed three months or prior to the first use thereafter." This allows somewhat more flexibility for equipment which may be used only infrequently.

§ *34.29 [Amended].*

The proposed amendment specified the requirement of audible and visible alarms on entrances to permanent radiographic installations. Commenters did not object particularly to having the alarm. However, commenters objected strongly to requiring that the alarm alert another individual besides the individual attempting entry. The NRC agrees that warning another individual is not necessary for radiography sources if other means of limiting access of unauthorized personnel are provided. The rule has been rewritten so that a second person besides the radiographer is not required if the licensee chooses to limit access of unauthorized personnel into the high radiation area by locking or maintaining direct surveillance as required by § 20.203(c) (2)(iii) or (4) and § 34.41. Note that personnel access may be controlled by direct surveillance under § 20.203(c)(4) since a permanent radiographic installation does not mean that there is a permanent high radiation area (i.e., 30 days or more).

Some commenters objected to not allowing an automatic source retraction device to substitute for the alarm. As written in effective form, the new § 34.29 allows an automatic source retraction device to substitute for the alarm system. If the installation has a source retraction device meeting the requirements of § 20.203(c)(2)(i), § 34.29 does not apply.

Other commenters objected to not allowing locked entrances to the installation as a substitute for the alarm. The NRC does not agree with this comment. Many overexposures have occurred when a radiographer unlocked the door to an installation and approached an exposed source without using a survey meter. Therefore, permanent installations must have an alarm even if locking of all entrances is planned. It should be noted that the alarm system required in § 34.29 is aimed more at protecting the radiographer himself than at unauthorized personnel. For this reason, the requirements in § 20.203(c) and § 34.41 on preventing such access by unauthorized personnel remain completely unchanged.

§ *34.31 [Amended]*

The amendment proposed to require written and field examinations for both radiographers and radiographers' assistants. The comment was made that oral examinations should be adequate for radiographers' assistants. In view of the high degree of supervision required for an assistant in the new § 34.44, the final rule has been changed to permit oral testing of assistants. The final rule also requires that copies of written tests and the dates of oral and field examinations be retained for three years.

§ *34.33 [Amended]*

The NRC proposed to amend § 34.33 to require annual accuracy checks on pocket dosimeters, with a ±30% accuracy criterion. The NRC also proposed to state that after an individual's pocket dosimeter had gone off-scale, the individual would be prohibited from further radiographic operations until the magnitude of the exposure had been evaluated.

Commenters said the accuracy check has little purpose and would not reduce radiation exposures. Commenters thought that since the pocket dosimeters are being manufactured to the stringent requirements of American National Standard N13.5–1972, "Performance Specifications for Direct Reading and Indirect Reading Pocket Dosimeters for X- and Gamma Radiation," that the proposed regulation is not necessary, particularly since defects in the dosimeters are generally either in a safe direction or else render the dosimeter completely unusable. The Commission, however, believes that some assurance of accuracy is necessary for pocket dosimeters and has decided to retain the proposed requirement. Thus, pocket dosimeters must be checked annually. To be acceptably accurate, the dose measured during the test must be within ±30% of the dose delivered during the test.

Commenters strongly objected to requiring that an individual with an off-scale dosimeter be removed from work since such action would be very costly and since dropping causes most dosimeters to go off-scale. The NRC has decided to delete this proposed requirement since it would do little to improve worker safety because the worker would not be restricted from work until after the exposure had already occured. In addition, it would be quite burdensome. Licensees should note, however, that under § 20.201, "Surveys," they are required to make evaluations of the radiation hazards incident to the use of a radioactive source. Thus it is required that the licensee evaluate the situation to determine the cause of the off-scale dosimeter before allowing the worker to resume work in a restricted area. If an overexposure has occurred, the important thing is to correct the hazard to prevent a repeat of the incident. So that this requirement is clearly understood, the Commission has decided to amend § 34.32, "Operating and Emergency Procedures," to specifically require licensees to have a procedure with steps that must be taken by radiography personnel in the event that a pocket dosimeter is found to be off-scale.

§ *34.41 (Amended)*

The existing wording of this section will not be changed. The proposed wording would have eliminated locking of doors as a substitute for direct surveillance to prevent unauthorized personnel from entering high radiation area. The comment was made that locking is a very practical means of limiting access by unauthorized personnel in many instances such as shipbuilding. The NRC agrees that locking can be more effective than direct surveillance in preventing unauthorized entry into a high radiation area. In many cases, such as areas that have multiple entry points, a momentary lapse of attention could allow someone to walk into the high radiation area unnoticed. Locks are a mechanical means not dependent on the constant attention of the radiographer. Therefore, the NRC will permit locking as an acceptable alternative. The section therefore will not be changed.

§ *34.43 (Amended)*

The proposed amendment of this section explicitly stated that the radiation survey to determine that a sealed source has returned to its shielded position after a radiographic exposure must include a survey of the source guide tube. Commenters said that such action is impractical in some situations, for example, when the cable runs through a shielded wall as in a permanent installation, through conduits between different areas, or when the device or guide tube is suspended on scaffolding. The NRC recognizes that sometimes the entire guide tube may not be accessible and that there are other survey techniques to demonstrate adequately that the source has returned to its shielded position.

The requirement to survey the guide tube does not mean that inaccessible portions must be surveyed. For example, if the guide tube runs through a thick concrete wall at a shielded facility, one need only survey to the wall. There would be no need to pull the guide tube out of the wall to make the survey. If the guide tube runs through a cable tray in a submarine under construction, it is only necessary to survey to the point where the guide tube enters the wall. If the guide tube is suspended on a scaffold, it is not necessary to climb up to the guide tube. The survey can be made from the ground.

A requirement to survey the entire circumference of the radiographic exposure device remains. This requirement means that the survey instrument should completely circle the device, especially the front of the device. It does not mean that the bottom of the device need be surveyed.

The proposed amendment of this section would also have added a specific requirement for surveying the perimeter of the restricted area. Numerous commenters said that the proposed wording was too inflexible for many situations, too vague, and potentially hazardous. The NRC has accepted this view. The requirement to survey restricted area boundaries will remain within the more general requirements of § 20.201, "Surveys." The proposed change is deleted.

§ 34.44 [Amended]

The proposed amendment defined in § 34.2 the supervision that a radiographer must give a radiographer's assistant. This proposed change met with stronger opposition than any other of the proposed changes. Many commenters expressed their belief that radiographers' assistants should be allowed to conduct routine surveys such as those of restricted area and radiation area boundaries without being watched by a radiographer. The NRC agrees that an assistant radiographer can quickly be trained to use a survey meter competently and can safely perform many of the less critical surveys, such as a survey of the boundary of the restricted area. The NRC also recognizes that prohibiting an assistant from independently performing such surveys would greatly decrease the usefulness of the assistant and place a large economic burden on licensees. Therefore, the amendment has been reworded so that the only survey during which the radiographer must watch the assistant is the survey to determine that the sealed source has returned to its shielded position after use. The radiographer should be watching the assistant to the extent that he is able to see that the assistant is carrying out his assigned functions in accordance with the instruction he has received. The requirements are being placed in a new § 34.44. It is more appropriate to include these requirements in a new section rather than with the definitions in § 34.2 as was proposed.

Appendix A [Amended]

No commenters objected to a proposed requirement that radiographers be instructed in case histories of radiography accidents. A recent NRC report, NUREG–0495, "Public Meeting on Radiation Safety for Industrial Radiographers," discusses such case histories.

Anyone wishing more detail on the development of these amendments may obtain an "Analysis of Public Comments on Proposed Amendments of 10 CFR Part 34" or a "Value/Impact Statement on Amendments of 10 CFR Part 34" by writing to Dr. Stephen A. McGuire, Occupational Health Standards Branch, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 within twelve months of this notice, or writing the NRC's Public Document Room thereafter.

In addition, a complete set of the public comments is available for inspection in the Public Document Room.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and Sections 552 and 553 of Title 5 of the United States Code, the following amendments of Title 10, Chapter I, Code of Federal Regulations, Part 34 are published as a document subject to codification.

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45 FR 2312
Published 1/11/80
Effective 3/3/80

10 CFR Part 34

Licenses for Radiography and Radiation Safety Requirements for Radiographic Operations; Change of Reference

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is changing a reference to 10 CFR Part 21 in 10 CFR Part 34. In § 34.31(a)(2) a licensee may not permit any person to act as a radiographer until that person has received copies of and instruction in, the regulations contained in the applicable sections of Parts 19 and 20. Previously published amendments to 10 CFR Part 34, to become effective on March 3, 1980, have deleted the reference to Part 21. This amendment replaces the deleted reference to Part 21 by placing it in a new subparagraph (l) of § 34.32.

EFFECTIVE DATE: March 3, 1980.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Alexander, Chief, Occupational Health Standards Branch, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Telephone (301–443–5975).

SUPPLEMENTARY INFORMATION: The amendment places in § 34.32(l) the requirement that radiographers receive instruction in the applicable sections of Part 21. Until now, this requirement has been included in § 34.31(a)(2); however, recent amendments to Part 34, which becomes effective March 3, 1980, delete reference to the instructions in the applicable sections of Part 21. Although the requirements of Part 21 are still binding on radiographers, the reference to Part 21 in Part 34 will insure that the requirement will not be overlooked by radiography licensees.

Since this amendment relates solely to a minor procedural matter and involves no substantive change, good cause exists for omitting notice of proposed rulemaking and public procedure thereon, and to make the amendment effective on March 3, 1980.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendment to Title 10, Chapter I, Code of Federal Regulations, Part 34 is published as a document subject to codification.

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46 FR 11804
Published 2/11/81
Effective 3/13/81

10 CFR Part 34

Disposal of Records of Pocket Dosimeter Readings

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: NRC regulations now provide that industrial radiography licensees must retain records of the daily readings of pocket dosimeters until the Commission authorizes disposal of the records. The NRC has decided that since readings of film badges and thermoluminescent dosimeters, which are retained indefinitely, constitute the long-term permanent records of the workers' dose, it is unnecessary for licensees to also retain pocket dosimeter readings indefinitely. This rule amends the regulation to provide that pocket dosimeter records need be retained for only two years.

EFFECTIVE DATE: March 13, 1981.

FOR FURTHER INFORMATION CONTACT: Dr. Stephen A. McGuire, Occupational Health Standards Branch, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone (301) 443–5970.

SUPPLEMENTARY INFORMATION: At present, § 34.33(b) of the Commission's regulations requires that industrial radiographers read their pocket dosimeters and record the readings daily. Licensees are now required by § 34.33(e) to keep these records "for inspection by the Commission until it authorizes their disposal." This amendment to § 34.33(e) specifies a two-year retention time for pocket dosimeter records.

The retention requirement for the film badge or thermoluminescent dosimeter (TLD) readings, which generally form the long-term record of the worker's dose, as required by § 20.401(a), remains unchanged. These dose records must be kept until the Commission authorizes their disposal. In practice, NRC has not authorized licensees to dispose of official dose records. Licensees giving up their licenses or going out of business are required by § 20.408(b) to submit a final termination report of all worker exposures to radiation incurred during employment.

The Commission believes that two years is an appropriate length of time to keep daily pocket dosimeter readings. The purpose of pocket dosimeter readings is to find out as soon as possible if anything has gone wrong during a day's work. These readings are also useful for comparison with the film badge or TLD report in case any unusual doses are recorded, and they assist NRC inspectors in determining if the pocket dosimeter was used and read daily. A two-year retention time allows NRC to inspect these records fully since the interval between inspection of radiography licensees is generally less than two years. The two-year retention time also is consistent with other record retention times in Part 34 for records of similar importance; for example, records of internal inspections (§ 34.11(d)), exposure device maintenance (§ 34.28(b)), permanent installation alarms (§ 34.29(c)), and the last survey of an exposure device before ending direct surveillance of an operation (§ 34.43(c)).

Note that this amendment to Part 34 in no way changes the licensee's obligation to maintain records of radiation exposures as required in § 20.401. Generally, the film badge or TLD reports form the basis for a radiographer's long-term dose estimate. However, it sometimes happens that the film badge or TLD is lost or cannot be read and thus no dose measurement can be made from the film badge or TLD. In this case the licensee will estimate the radiographer's dose by whatever other means are available. Both daily pocket dosimeter readings and radiation survey results are obvious sources of the dose information. As required in § 20.401 (a) and (c), records of the radiographer's estimated dose must be maintained on Form NRC-5 or equivalent until the Commission authorizes their disposal.

The public was invited to submit written comments on the proposed rule by July 28, 1980. Six comments were received, and all supported the proposed amendment. Therefore, the Commission is adopting the final rule in the form identical to the proposed amendment.

Under the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendment to Title 10, Chapter I, Code of Federal Regulations, Part 34 is published as a document subject to codification.

49 FR 19623
Published 5/9/84
Effective 5/9/84

Information Collection Requirements; Display of OMB Control Numbers

See Part 0 Statements of Consideration

49 FR 27923
Published 7/9/84
Effective 7/9/84

Application Consolidation to NRC Form 313; Application for Material License

See Part 30 Statements of Consideration

PART 35

HUMAN USES OF BYPRODUCT MATERIAL

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35.2 License requirements.
35.3 Definitions.
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SPECIFIC LICENSES

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35.14 Specific licenses for certain groups of medical uses of byproduct material.

SPECIAL REQUIREMENTS FOR TELETHERAPY LICENSEES

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GENERAL LICENSES

35.31 General license for medical use of certain quantities of byproduct material.

35.41 Definition of a misadministration.
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35.45 Rights and duties of licensees.

SCHEDULES

35.100 Schedule A—Groups of medical uses of byproduct material.

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended: (42 U.S.C. 2111, 2201, 2232, 2233): Section 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 35.2, 35.14 (b), (e) and (f), 35.21(a), 35.22(a), 35.24, and 35.31 (b) and (c) are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§ 35.14(b)(5) (ii), (iii) and (v) and (f)(2), 35.27 and 35.31(d) are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

§ 35.1 Purpose and scope.

This part prescribes regulations governing the licensing of byproduct material for human uses. It includes special requirements for issuance of specific licenses authorizing human use of byproduct material, general licenses for human use of byproduct material of specified types and forms, and certain regulations governing the holders of such specific and general licenses. The provisions and requirements of this part are in addition to, and not in substitution for, other requirements of this chapter. In particular, the provisions of Part 30 of this chapter apply to applications and licenses subject to this part.

30 FR 8185

§ 35.2 License requirements.

No person subject to the regulations in this chapter shall receive, possess, use, or transfer byproduct material for any human use except in accordance with a specific or general license issued pursuant to the regulations in this part and Parts 30 and 32 or 33 of this chapter.

35 FR 6425

§ 35.3 Definitions.

As used in this part:

(a) "Human use" means the internal or external administration of byproduct material, or the radiation therefrom, to human beings;

(b) "Physician" means an individual licensed by a State or territory of the United States, the District of Columbia or the Commonwealth of Puerto Rico to dispense drugs in the practice of medicine.

30 FR 8185

§ 35.4 Application form for specific licenses.

A person may file an application for specific license for human use under §§ 35.11, 35.12, and 35.13 of this part in duplicate on NRC Form 313, "Application for Material License," in accordance with the provisions of § 30.32 of this chapter.

§ 35.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). OMB has approved the information collection requirements contained in this part under control number 3150–0010.

(b) The approved information collection requirements contained in this part appear in §§ 35.12, 35.14, 35.27, 35.42, 35.43, and 35.44.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In §§ 35.4, 35.11, 35.12, and 35.13 Form NRC–313M is approved under control number 3150–0041.

(2) In § 35.31, Form NRC–482 is approved under control number 3150–0022.

§ 35.11 Specific licenses for human use of byproduct material in insitutions.

An application by an institution for a specific license on Form NRC–313 for human use of byproduct material will be approved if:

49 FR 19623

(a) The applicant satisfies the general requirements specified in §30.33 of this chapter;

30 FR 8185

(b) The applicant has appointed a radiation safety committee to oversee the use of licensed material throughout the institution and to review the institution's radiation safety program. Membership of the committee must incude at least the following: an authorized user for each type of use permitted by the license, a representative of the nursing staff, a representative of the institution's management, and the Radiation Safety Officer;

47 FR 40149

(c) The applicant possesses adequate facilities for the clinical care of patients;

(d) The physician designated on the application as the individual user has substantial experience in the proposed use, the handling and administration of radioisotopes and, where applicable, the clinical management of radioactive patients; and

(e) If the application is for a license to use unspecified quantities or multiple types of byproduct material, the applicant has previously received a reasonable number of licenses for a variety of byproduct materials for a variety of human uses.

30 FR 8185

§ 35.12 Specific licenses to individual physicians for human use of byproduct material.

(a) An application by an individual physician or groups of physicians for a specific license on Form NRC–313 for human use of byproduct material will be approved if:

49 FR 19623

(1) The applicant satisfies the general requirements specified in §30.33 of this chapter;

(2) The application is for use in the applicant's practice in an office(s) outside a medical institution;

42 FR 36240

(3) The applicant has access to a hospital possessing adequate facilities to hospitalize and monitor the applicant's radioactive patients whenever it is advisable; and

(4) The applicant has extensive experience in the proposed use, the handling and administration of radioisotopes, and where applicable, the clinical management of radioactive patients. (The physician(s) shall furnish suitable evidence of such experience with the application. A statement from the medical isotope committee in the institution where the applicant acquired experience, indicating its amount and nature, may be submitted as evidence of such experience.)

(b) The Commission will not approve an application by an individual physician or group of physicians for a specific license to receive, possess or use byproduct material on the premises of a medical institution unless:

(1) The use of byproduct material is limited to:

(i) The administration of radiopharmaceuticals for diagnostic or therapeutic purposes;

(ii) The performance of diagnostic studies on patients to whom a radiopharmaceutical has been administered;

(iii) The performance of in vitro diagnostic studies; or

(iv) The calibration and quality control checks of radioactive assay instrumentation, radiation safety instrumentation, and diagnostic instrumentation;

(2) The physician brings the byproduct material with him and removes the byproduct material when he departs. (The institution cannot receive, possess or store byproduct material other than the amount of material remaining in the patient); and

(3) The medical institution does not hold a byproduct material license under §35.11.

§ 35.13 Specific licenses for human use of byproduct material in sealed sources.

An application for a specific license on Form NRC-313 for use of a sealed source for human use will be approved if:

(a) The applicant satisfies the general requirements specified in §30.33 of this chapter; and

(b) The applicant or, if the application is made by an institution, the individual user (1) has specialized training in the therapeutic use of the radioactive device considered (teletherapy unit, beta applicator, etc.) or has experience equivalent to such training; and (2) is a physician.

§ 35.14 Specific licenses for certain groups of medical uses of byproduct material.

(a) Subject to the provisions of paragraphs (b), (c), and (d) of this section, an application for a specific license pursuant to §35.11, §35.12, or §35.13 for any medical use or uses of byproduct material specified in one or more of Groups I to VI, inclusive, of §35.100 will be approved for all of the uses within the group or groups which include the use or uses specified in the application if:

(1) The applicant satisfies the requirements of §35.11, §35.12, or §35.13;

(2) The applicant, or the physician designated in the application as the individual user, has adequate clinical experience in the types of uses included in the group or groups;

(3) The applicant or the physicians and all other personnel who will be involved in the preparation and use of the byproduct material have adequate training and experience in the handling of radioactive material appropriate to their participation in the uses included in the group or groups;

(4) The applicant's radiation detection and measuring instrumentation is adequate for conducting the procedures involved in the uses included in the group or groups;

(5) The applicant's radiation safety operating procedures are adequate for handling and disposal of the radioactive material involved in the uses included in the group or groups;

(b) Any licensee who is authorized to use byproduct material pursuant to one or more groups in §§35.14(a) and 35.100 is subject to the following conditions:

(1) For Groups I, II, IV, and V no licensee shall receive, possess, or use byproduct material except as a radiopharmaceutical manufactured in the form to be administered to the patient, labeled, packaged, and distributed in accordance with:

(i) A specific license issued pursuant to §32.72 of this chapter; or

(ii) A specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations; or

(iii) An application filed with the Atomic Energy Commission pursuant to §32.72 of this chapter or with an Agreement State pursuant to equivalent State regulations on or before October 15, 1974 for a license to manufacture and distribute a radiopharmaceutical that the applicant distributed commercially on or before August 16, 1974, on which application the Atomic Energy Commission or the Nuclear Regulatory Commission or the Agreement State has not acted.

(2) For Group III, no licensee shall receive, possess, or use generators or reagent kits containing byproduct material or shall use reagent kits that do not contain byproduct material to prepare radiopharmaceuticals containing byproduct material, except:

(i) Reagent kits not containing byproduct material that are approved by the Commission or the Atomic Energy Commission or an Agreement State for use by persons licensed pursuant to this §35.14 and Group III of Schedule A, §35.100 or equivalent Agreement State regulations; or

(ii) Generators or reagent kits containing byproduct material that are manufactured, labeled, packaged, and distributed in accordance with a specific license issued pursuant to §32.73 of this chapter or by an Agreement State pursuant to equivalent State regulations; or

(iii) Generators or reagent kits that the manufacturer distributed on or before August 16, 1974 for which an application for license or approval was filed with the Atomic Energy Commission pursuant to §32.73 of this chapter or with an Agreement State pursuant to equivalent State regulations on or before October 15, 1974 on which application the Atomic Energy Commission or the Nuclear Regulatory Commission or the Agreement State has not acted.

(3) For Group VI no licensee shall receive, possess, or use byproduct material except as contained in a source or device that has been manufactured, labeled, packaged, and distributed in accordance with:

(i) A specific license issued pursuant to §32.74 of this chapter; or

(ii) A specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations; or

(iii) An application filed with the Atomic Energy Commission pursuant to §32.74 of this chapter or with an Agreement State pursuant to equivalent State regulations on or before October 15, 1974 for a license to manufacture a source or device that the applicant distributed commercially on or before August 16, 1974 on which application the Atomic Energy Commission or the Nuclear Regulatory Commission or the Agreement State has not acted.

40 FR 8774

(4) For Group III, any licensee using generators or reagent kits shall:

(i) Elute the generator, or process radioactive material with the reagent kit, in accordance with instructions approved by the Nuclear Regulatory Commission or an Agreement State and furnished by the manufacturer on the label attached to or in the leaflet or brochure that accompanies the generator or reagent kit;

(ii) Before administration to patients, cause each elution or extraction of technetium-99m from a molybdenum-99/technetium-99m generator to be tested to determine either the total molybdenum-99 activity or the concentration of molybdenum-99. This testing shall be conducted according to written procedures and by personnel who have been specifically trained to perform the test;

(iii) Prohibit the administration to patients of technetium-99m containing more than 1 microcurie of molybdenum-99 per millicurie of technetium-99m, or more than 5 microcuries of molybdenum-99 per administered dose, at the time of administration; and

(iv) Maintain for 3 years for Commission inspection records of the molybdenum-99 test conducted on each elution from the generator.

45 FR 41393

(5) For Group VI any licensee who possesses and uses sources or devices containing byproduct material shall:

(i) Cause each source or device containing more than 100 microcuries of byproduct material with a half-life greater than thirty days, except iridium-192 seeds encased in nylon ribbon, to be tested for contamination and/or leakage at intervals not to exceed six months or at such other intervals as are approved by the Nuclear Regulatory Commission or an Agreement State and described by the manufacturer on the label attached to the source, device or permanent container thereof, or in the leaflet or brochure which accompanies the source or device. Each source or device shall be so tested prior to its first use unless the supplier furnishes a certificate that the source or device has been so tested within six months prior to the transfer;

(ii) Assure that the test required by paragraph (b)(5)(i) of this section is capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the source or from the surfaces of the device in which the source is permanently or semipermanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission;

(iii) If the test required by paragraph (b)(5)(i) of this section reveals the presence of 0.005 microcurie or more of removable contamination, immediately withdraw the source from use and cause it to be decontaminated and repaired or to be disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the test with the appropriate Nuclear Regulatory Commission Inspection and Enforcement Regional Office listed in Appendix D of Part 20 of this chapter, describing the equipment involved, the test results, and the corrective action taken.

39 FR 26143

Copies of such report shall be sent to the Director of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555;

41 FR 16445

(iv) Follow the radiation safety and handling instructions approved by the Nuclear Regulatory Commission or an Agreement State and furnished by the manufacturer on the label attached to the source, device or permanent container thereof, or in the leaflet or brochure that accompanies the source or device, and maintain such instruction in a legible and conveniently available form;

39 FR 26143

(v) Conduct a quarterly physical inventory to account for all sources and devices received and possessed. Records of the inventories shall be maintained for inspection by the Commission and shall include the quantities and kinds of byproduct material, location of sources and devices, and the date of the inventory;

(vi) Assure that needles or standard medical applicator cells containing cobalt-60 as wire are not opened while in the licensee's possession unless specifically authorized by a license issued to him by the Atomic Energy Commission or the Commission;

39 FR 26143

(vii) Assure that patients treated with cobalt-60, cesium-137 or iridium-192 implants remain hospitalized until a source count and a radiation survey of the patient confirm that all implants have been removed.

43 FR 55346

(6) Except for those radiopharmaceuticals listed in paragraph (b)(7) of this section, for Groups I, II, and III any licensee using byproduct material for clinical procedures other than those specified in the product labeling (package insert) shall comply with the product labeling regarding:

(i) Chemical and physical form;

(ii) Route of administration; and

(iii) Dosage range.

(7) The following radiopharmaceutical(s) when used for the listed clinical procedure(s), are not subject to the restrictions in paragraph (b)(6) of this section:

(i) Technetium-99m pentetate as an aerosol for lung function studies.

(8) Radioactive aerosols must be administered with a closed, shielded system that either is vented to the outside atmosphere through an air exhaust or provides for collection and disposal of the aerosol.

48 FR 5217

(c) Any licensee who is licensed pursuant to paragraph (a) of this section for one or more of the medical use groups in §35.100 also is authorized to use byproduct material under the general license in §31.11 of this chapter for the specified in vitro uses without filing Form NRC-483 as required by §31.11(b); *Provided*, That the licensee is subject to the other provisions of §31.11.

(d) Any licensee who is licensed pursuant to paragraph (a) of this section for one or more of the medical use groups in §35.100 also is authorized, subject to the provisions of paragraphs (e) and (f) of this section, to receive, possess, and use for calibration and reference standards:

(1) Any byproduct material listed in Group I, Group II, or Group III of Schedule A, §35.100, with a half-life not longer than 100 days, in amounts not to exceed 15 millicuries total;

(2) Any byproduct material listed in Group I, Group II, or Group III of Schedule A, §35.100 with half-life greater than 100 days in amounts not to exceed 200 microcuries total;

(3) Technetium-99m in amounts not to exceed 30 millicuries;

(4) Any byproduct material, in amounts not to exceed 3 millicuries per source, contained in calibration or reference sources that have been manufactured, labeled, packaged, and distributed in accordance with:

39 FR 26143

(i) A specific license issued by the Commission pursuant to §32.74 of this chapter; or

(ii) A specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations; or

(iii) An application filed with the Atomic Energy Commission pursuant to §32.74 of this chapter or with an Agreement State pursuant to equivalent State regulations on or before October 15, 1974 for a license to manufacture a source that the applicant distributed commercially on or before August 16, 1974, on which application the Atomic Energy Commission or the Nuclear Regulatory Commission or the Agreement State has not acted.

(e)(1)(i) Any licensee who possesses sealed sources as calibration or reference sources pursuant to paragraph (d) of this section shall cause each sealed source containing byproduct material, other than hydrogen-3, with a half-life greater than thirty days in any form other than gas to be tested for leakage and/or contamination at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, the sealed source shall not be used until tested, *Provided, however*, That no leak tests are required when:

(*a*) The source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material, or

(*b*) The sealed source is stored and is not being used; such sources shall, however, be tested for leakage prior to any use or transfer unless they have been leak tested within six months prior to the date of use or transfer.

(2) The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently mounted or stored on which contamination might be expected to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission.

39 FR 26143

(3) If the leak test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Parts 20 and 30 of this chapter. A report shall be filed within 5 days of the test with the appropriate Nuclear Regulatory Commission Inspection and Enforcement Regional Office listed in Appendix D of Part 20 of this chapter, with a copy to the Director of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555,[†] describing the equipment involved, the test results, and the corrective action taken;

(f) Any licensee who possesses and uses calibration and reference sources pursuant to paragraph (d)(4) of this section shall:

(1) Follow the radiation safety and handling instructions approved by the Atomic Energy Commission, the Commission, or an Agreement State and furnished by the manufacturer on the label attached to the source, or permanent container thereof, or in the leaflet or brochure that accompanies the source, and maintain such instruction in a legible and conveniently available form.

(2) Conduct a quarterly physical inventory to account for all sources received and possessed. Records of the inventories shall be maintained for inspection by the Commission and shall include the quantities and kinds of byproduct material, location of sources, and the date of the inventory.

39 FR 26143

[†] Amended 41 FR 16445.

SPECIAL REQUIREMENTS FOR TELETHERAPY LICENSEES

§ 35.21 Requirement to perform full calibration measurements of teletherapy units.

(a) Any licensee authorized under § 35.13 to use teletherapy units for treating humans shall cause full calibration measurements to be performed on each teletherapy unit:

(1) Prior to the first use of the unit for treating humans;

(2) Prior to treating humans:

(i) Whenever spot-check measurements indicate that the output value differs by more than 5 percent from the value obtained at the last full calibration corrected mathematically for physical decay;

(ii) Following replacement of the radiation source or following reinstallation of the teletherapy unit in a new location;

(iii) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

44 FR 1722

(3) At intervals not exceeding one year.

(b) Full calibration measurements required by paragraph (a) of this section shall include determination of:

(1) The exposure rate or dose rate to an accuracy within ±3 percent for the range of field sizes and for the range of distances (or for the axis distance) used in radiation therapy;

(2) The congruence between the radiation field and the field indicated by the light beam localizing device;

(3) The uniformity of the radiation field and its dependence upon the orientation of the useful beam;

(4) Timer accuracy; and

(5) The accuracy of all distance measuring devices used for treating humans.

(c) Full calibration measurements shall be made in accordance with the procedures recommended by the Scientific Committee on Radiation Dosimetry of the American Association of Physicists in Medicine (*Physics in Medicine and Biology*, Vol. 16, No. 3, 1971, pp. 379-396).[1]

(d) The exposure rate or dose rate values determined in paragraph (b)(1) of this section shall be corrected mathematically for physical decay for intervals not exceeding one month.

(e) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (d) of this section shall be performed by an expert qualified by training and experience in accordance with § 35.24.

§ 35.22 Requirement to perform periodic spot-check measurements of teletherapy units.

(a) Any licensee authorized under § 35.13 to use teletherapy units for treating humans shall cause spot-check measurements to be performed on each teletherapy unit at intervals not exceeding one month.

(b) Spot-check measurements required by paragraph (a) of this section shall include determination of:

(1) Timer accuracy;

(2) The congruence between the radiation field and the field indicated by the light beam localizing device;

44 FR 1722

(3) The accuracy of all distance measuring devices used for treating humans;

(4) The exposure rate, dose rate, or a quantity related in a known manner to these rates for one typical set of operating conditions; and

(5) The difference between the measurement made in paragraph (b)(4) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

(c) Spot-check measurements required by paragraph (a) of this section shall be performed in accordance with procedures established by an expert qualified by training and experience in accordance with § 35.24. (A qualified expert need not actually perform the spot-check measurements.) If a qualified expert does not perform the spot-check measurements, the results of the spot-check measurements shall be reviewed by a qualified expert within 15 days.

§ 35.23 Requirement to calibrate instruments used for full calibration and spot-check measurements.

(a) Full calibration measurements required by § 35.21 shall be performed using a dosimetry system that has been calibrated by the National Bureau of Standards or by a Regional Calibration Laboratory accredited by the American Association of Physicists in Medicine. The dosimetry system shall have been calibrated within the previous two years and after any servicing that may have affected system calibration.

(b) Spot-check measurements required by § 35.22 shall be performed using a dosimetry system that has been calibrated in accordance with paragraph (a) of this section. Alternatively, a dosimetry system used solely for spot-check measurements may be calibrated by direct intercomparison with a system that has been calibrated in accordance with paragraph (a) of this section. This alternative calibration method shall have been performed within the previous one year and after each servicing that may have affected system calibration. Dosimetry systems calibrated by this alternative method shall not be used for full calibration measurements.

§ 35.24 Qualified expert.

The licensee shall determine if a person is an expert qualified by training and experience to calibrate a teletherapy unit and establish procedures for (and review the results of) spot-check measurements. The licensee shall determine that the qualified expert:

44 FR 1722

(a) Is certified by the American Board of Radiology in Therapeutic Radiological Physics, Radiological Physics, Roentgen-Ray and Gamma-Ray Physics, or X-ray and Radium Physics; or

(b) Has the following[2] minimum training and experience:

(1) A Master's or Doctor's degree in physics, biophysics, radiological physics or health physics;

(2) One year of full-time training in therapeutic radiological physics; and

(3) One year of full-time experience in a radiotherapy facility including personal calibration and spot check of at least one teletherapy unit.

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[1] This incorporation by reference provision was approved by the Acting Director of the Federal Register on August 6, 1976. Copies are available for inspection or may be obtained from U.S. Nuclear Regulatory Commission, Public Document Room, 1717 H Street, NW., Washington, D.C. 20555.

[2] Licensees that have their teletherapy units calibrated by persons who do not meet these criteria for minimum training and experience may request a license amendment excepting them from the requirements of § 35.24. The request, accompanied by the appropriate amendment fee (§ 170.31 of 10 CFR Part 170), should include the name of the proposed qualified expert, a description of his training and experience including information similar to that specified in § 35.24(b), reports of at least one calibration and spot-check program based on measurements personally made by the proposed expert within the last 10 years, and written endorsement of the technical qualifications of the proposed expert from personal knowledge by a physicist certified by the American Board of Radiology in one of the specialities listed in § 35.24(a). The individual's qualifications will be evaluated by NRC's consultants in medical physics. The amendment request should be addressed to: License Management Branch, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

§ 35.25 Requirements to install a permanent radiation monitor in teletherapy rooms and to use portable survey instruments or audible alarm dosimeters.

(a) Each licensee authorized under § 35.13 to use teletherapy units for treating humans shall install a permanent radiation monitor in each teletherapy room for continous monitoring of beam status.

(b) Each radiation monitor must be capable of providing visible notice of a teletherapy unit malfunction that may result in an exposed or partially exposed source. The visable indicator of high radiation levels must be located so as to be observable by a person entering the treatment room.

(c) Each radiation monitor must be equipped with an emergency power supply separate from the power supply to the teletherapy unit. This emergency power supply may be a battery system.

(d) Each radiation monitor must be tested for proper operation each day before the teletherapy unit is used for treatment of patients.

(e) If a radiation monitor is inoperable for any reason, any person entering the teletherapy room shall use a properly operating portable survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism that may have resulted in an exposed or partially exposed source. Survey instruments or dosimeters must be tested daily before use.

48 FR 2115

§ 35.26 Inspection and servicing of the source exposure mechanism; relief granted by certain license conditions.

(a) The licensee shall cause each teletherapy unit used to treat humans to be fully inspected and serviced during source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(b) Inspection and servicing of the teletherapy unit shall be performed by persons specifically licensed to do so by the Commission or an Agreement State.

(c) Amendments to teletherapy licenses in effect as of March 4, 1983, which extended the time interval for the inspection and servicing requirement of paragraph (a) of this section shall remain in effect and are not rescinded by this section.

§35.27 Records.

The licensee shall maintain, for inspection by the Commission, records of the measurements, tests, corrective actions, inspection and servicing of the teletherapy unit, and instrument calibrations made under §§ 35.21 through 35.26 and records of the licensee's evaluation of the qualified expert's training and experience made under § 35.24.

(a) The following records must be preserved for five years after completion of the full calibration or after inspection and servicing:

(1) Full calibration measurements reports made under § 35.21.

(2) Records of calibration of the instruments used to make these measurements under § 35.23.

(3) Records of inspection and servicing of the teletherapy unit under § 35.26.

48 FR 2115

(b) Records of (1) spot-check measurements and corrective actions under § 35.22 and (2) calibration of instruments used to make spot-check measurements under § 35.23, shall be preserved for two years after completion of the spot-check measurements and corrective actions.

(c) Records of the licensee's evaluation of the qualified expert's training and experience under § 35.24 shall be preserved for five years after the qualified expert's last performance of a full calibration on the licensee's teletherapy unit.

GENERAL LICENSES

§ 35.31 General license for medical use of certain quantities of byproduct material.

(a) A general license is hereby issued to any physician to receive, possess, transfer, or use for any of the following stated diagnostic uses, in accordance with the provisions of paragraphs (b), (c), and (d) of this section, the following byproduct materials in capsules, disposable syringes or other forms of prepackaged individual doses:

(1) Iodine-131 as sodium iodide (NaI^{131}) for measurement of thyroid uptake;

(2) Iodine-131 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;

(3) Iodine-125 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;

(4) Cobalt-58 for the measurement of intestinal absorption of cyanocobalamin;

(5) Cobalt-60 for the measurement of intestinal absorption of cyanocobalamin;

(6) Chromium-51 as sodium radiochromate for determination of red blood cell volumes and studies of red blood cell survival time.

Note: Section 32.70 of this chapter requires manufacturers of radiopharmaceuticals which are under the general license in this paragraph to include the following statement in the label affixed to the container or in the leaflet or brochure which accompanies the radiopharmaceutical:

This radioactive drug may be received, possessed, and used only by physicians licensed to dispense drugs in the practice of medicine. Its receipt, possession, use, and transfer are subject to the regulations and a general license of the United States Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

(Name of manufacturer)

30 FR 8185

(b) No physician shall receive, possess, use, or transfer byproduct material pursuant to the general license established by paragraph (a) of this section until he has filed Form NRC-482, "Registration Certificate–Medical Use of Byproduct Material Under General License" with the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C., 20555, and received from the Commission a validated copy of the Form NRC-482 with registration number assigned. The registrant shall furnish on Form NRC-482 the following information and such other information as may be required by that form.

(1) Name and address of the registrant;

(2) A statement that the registrant is a duly licensed physician authorized to dispense drugs in the practice of medi-

cine, and specifying the license number and the State in which such license is valid; and

(3) A statement that the registrant has appropriate radiation measuring instruments to carry out the diagnostic procedures for which he proposes to use byproduct material under the general license of §35.31 of this chapter and that he is competent in the use of such instruments.

(c) A physician who receives, possesses, or uses a pharmaceutical containing byproduct material pursuant to the general license established by paragraph (a) of this section shall comply with the following:

(1) He shall not possess at any one time, pursuant to the general license in paragraph (a) of this section, more than:

(i) 200 microcuries of iodine-131,

(ii) 200 microcuries of iodine-125,

(iii) 5 microcuries of cobalt-58,

(iv) 5 microcuries of cobalt-60, and

(v) 200 microcuries of chromium-51.

(2) He shall store the pharmaceutical until administered in the original shipping container or a container providing equivalent radiation protection;

30 FR 8185

(3) He shall use the pharmaceutical only for the uses authorized by paragraph (a) of this section;

(4) He shall not administer the pharmaceutical to a woman with confirmed pregnancy or to a person under 18 years of age;

(5) He shall not transfer the byproduct material to a person who is not authorized to receive it pursuant to a license issued by the Commission or an Agreement State, or in any manner other than in the unopened, labeled shipping container as received from the supplier, except by administering it to a patient.

(d) The registrant possessing or using byproduct material under the general license of paragraph (a) shall report in duplicate to the Director of Nuclear Material Safety and Safeguards any changes in the information furnished by him in the "Registration Certificate—Medical Use of Byproduct Material Under General License," Form NRC-482. The report shall be submitted within 30 days after the effective date of such change.

(e) Any person using byproduct material pursuant to the general license of paragraph (a) of this section is exempt from the requirements of Parts 19, 20, and 21* of this chapter with respect to the byproduct materials covered by the general license.

Misadministration Reports and Records

§ 35.41 Definition of a misadministration.

For this part, misadministration means the administration of:

(a) A radiopharmaceutical or radiation from a sealed source other than the one intended;

(b) A radiopharmaceuted or radiation to the wrong patient;

(c) A radiopharmaceutical or radiation by a route of administration other than that intended by the prescribing physician;

(d) A diagnostic dose of a radiopharmaceutical differing from the prescribed dose by more than 50 percent;

(e) A therapeutic dose of a radiopharmaceutical differing from the prescribed dose by more than 10 percent; or

(f) A therapeutic radiation dose from a sealed source such that errors in the source calibration, time of exposure, and treatment geometry result in a calculated total treatment dose differing from the final prescribed total treatment dose by more than 10 percent.

45 FR 31701

§ 35.42 Reports of therapy misadministrations.

(a) *Immediate telephone report.* When a misadministration involves any therapy procedure, the licensee shall notify, by telephone only, the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter. The licensee shall also notify the referring physician of the affected patient and the patient or a responsible relative (or guardian), *unless* the referring physician personally informs the licensee either that he will inform the patient or that, in his medical judgment, telling the patient or the patient's responsible relative (or guardian) would be harmful to one or the other, respectively. These notifications shall be made within 24 hours after the licensee discovers the misadministration. If the referring physician, patient** or the patient's responsible relative or guardian cannot be reached within 24 hours, the licensee shall notify them as soon as practicable. The licensee is not required to notify the patient or the patient's responsible relative or guardian without first consulting the referring physician; however, the licensee shall not delay medical care for the patient because of this.

(b) *Written report.* Within 15 days after the initial therapy misadministration report to NRC, the licensee shall report, in writing, to the NRC Regional Office initially telephoned and to the refering physician, and furnish a copy of the report to the patient or the patient's responsible relative (or guardian) if either was previously notified by the licensee under paragraph (a) of this section. The written report shall include the licensee's name; the referring physician's name; a brief description of the event; the effect on the patient; the action taken to prevent recurrence; whether the licensee informed the patient or the patient's responsible relative (or guardian), and if not, why not. The report shall not include the patient's name, or other information which could lead to identification of the patient.

§ 35.43 Reports of diagnostic misadministrations.

When a misadministration involves a diagnostic procedure, the licensee shall notify, in writing, the referring physician and the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter. Licensee reports of diagnostic misadministrations are due within 10 days after the end of the calendar quarters (defined by March, June, September, and December) in which they occur. These written reports shall include the licensee's name; the referring physician's name, a description of the event; the effect on the patient; and the action taken to prevent recurrence. The report should not include the patient's name or other information which could lead to identification of the patient.

45 FR 31701

§ 35.44 Records of all misadministrations.

Each licensee shall maintain for Commission inspection, records of all misadministrations of radiopharmaceuticals or radiation from teletherapy or brachytherapy sources. These records shall contain the names of all individuals involved in the event (including the physician, allied health personnel, the patient, and the patient's refering physician), the patient's social security number, a brief description of the event, the effect on the patient, and the action taken to prevent recurrence. These records shall be preserved until the Commission authorizes their disposition.

§ 35.45 Rights and duties of licensees.

Aside from the notification requirement, nothing in this section shall affect any rights or duties of licensees and physicians in relation to each other, patient or responsible relatives (or guardians).

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*Amended 42 FR 28891.

** Amended 45 FR 39829

SCHEDULES

§ 35.100 Schedule A—Groups of medical uses of byproduct material.

(a) *Group I.* Use of prepared radiopharmaceuticals for certain diagnostic studies involving measurements of uptake, dilution and excretion. This group does not include imaging or localization studies.

(1) Iodine-131 as sodium iodide, iodinated human serum albumin, labeled rose bengal, triolein, or sodium iodohippurate;

(2) Iodine-125 as sodium iodide, iodinated human serum albumin, oleic acid or sodium iothalamate;

(3) Cobalt-58 as labeled cyanocobalamin;

(4) Cobalt-60 as labeled cyanocobalamin;

(5) Chromium-51 as sodium chromate or labeled human serum albumin;

(6) Iron-59 as citrate;

(7) Technetium-99m as pertechnetate; and

(8) Any byproduct material in a radiopharmaceutical and for a diagnostic use involving measurements of uptake, dilution or excretion for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the Food and Drug Administration (FDA).

(b) *Group II.* Use of prepared radiopharmaceuticals for diagnostic imaging and localization studies

(1) Iodine-131 as sodium iodide, iodinated human serum albumin, macroaggregated iodinated human serum albumin, colloidal (microaggregated) iodinated human serum albumin, rose benegal or sodium iodohippurate;

(2) Iodine-125 as sodium iodide or fibrinogen;

(3) Chromium-51 as human serum albumin;

(4) Gold-198 in colloidal form;

(5) Mercury-197 as chlormerodrin;

(6) Mercury-203 as chlormerodrin;

(7) Selenium-75 as selenomethionine;

(8) Strontium-85 as nitrate;

(9) Technetium-99m as pertechnetate, sulfur colloid or macroaggregated human serum albumin;

(10) Ytterbium-169 as pentatate sodium;

(11) Indium-113m as chloride;

(12) Any byproduct material in a radiopharmaceutical prepared from a reagent kit listed in paragraph (c)(4) of this section; and

(13) Any byproduct material in a radiopharmaceutical and for a diagnostic use involving imaging or localizing for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the Food and Drug Administration (FDA).

(c) *Group III.* Use of generators and reagent kits for the preparation and use of radiopharmaceuticals containing byproduct material for certain diagnostic studies.

(1) Molybdenum-99/technetium-99m generators for the elution of technetium-99m as pertechnetate;

(2) Technetium-99m as pertechnetate for use with reagent kits for preparation and use of radiopharmaceuticals containing technetium-99m as provided in paragraphs (c) (4) and (5) of this section;

(3) Tin-113/indium-113m generators for the elution of the indium-113m as chloride;

(4) Reagent kits for preparation of technetium-99m labeled:

(i) Sulfur colloid;

(ii) Pentatate sodium;

(iii) Human serum albumin microspheres;

(iv) Polyphosphates;

(v) Macroaggregated human serum albumin;

(vi) Etidronate sodium;

(vii) Stannous pyrophosphate;

(viii) Human serum albumin;

(ix) Medronate sodium;

(x) Gluceptate sodium;

(xi) Oxidronate sodium;

(xii) Disofenin;

(xiii) Succimer;

(xiv) Albumin colloid; and

(5) Any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing byproduct material for which generator or reagent kit a "Notice of Claimed Investigational Exemption of a New Drug" (IND) has been accepted by the Food and Drug Administration (FDA).

(d) *Group IV.* Use of prepared radiopharmaceuticals for certain therapeutic uses that do not normally require hospitalization for purposes of radiation safety:

(1) Iodine-131 as iodide for treatment of hyperthyroidism** and cardiac dysfunction;

(2) Phosphorus-32 as soluble phosphate for treatment of polycythemia vera, leukemia and bone metastases;

(3) Phosphorus-32 as colloidal chromic phosphate for intracavitary treatment of malignant effusions;

(4) Any byproduct material in a radiopharmaceutical and for a therapeutic use not normally requiring hospitalization for purposes of radiation safety for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the Food and Drug Administration (FDA).

(e) *Group V.* Use of prepared radiopharmaceuticals for certain therapeutic uses that normally require hospitalization for purposes of radiation safety:

(1) Gold-198 as colloid for intracavitary treatment of malignant effusions;

(2) Iodine-131 as iodide for treatment of thyroid carcinoma;

(3) Any byproduct material in a radiopharmaceutical and for a therapeutic use normally requiring hospitalization for radiation safety reasons for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the Food and Drug Administration (FDA).

(f) *Group VI.* Use of sources and devices containing byproduct material for certain medical uses:

(1) Americium-241 as a sealed source in a device for bone mineral analysis;

(2) Cesium-137 encased in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

(3) Cobalt-60 encased in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

(4) Gold-198 as seeds for interstitial treatment of cancer;

(5) Iodine-125 as a sealed source in a device for bone mineral analysis;

(6) Iridium-192 as seeds encased in nylon ribbon for interstitial treatment of cancer;

(7) Strontium-90 sealed in an applicator for treatment of superficial eye conditions;

(8) Iodine-125 as seeds for interstitial treatment of cancer.

(9) Iodine-125 as a sealed source in a portable device for bone imaging and foreign body detection.

[Note removed 49 FR 19623]

**Amended 40 FR 26679.

UNITED STATES NUCLEAR REGULATORY COMMISSION

RULES and REGULATIONS

TITLE 10, CHAPTER 1, CODE OF FEDERAL REGULATIONS—ENERGY

PART
35

HUMAN USES OF BYPRODUCT MATERIAL

PROPOSED RULE MAKING

46 FR 43840
Published 9/1/81
Comment period expires November 30, 1981. Comments received after November 30, 1981 will be considered if it is practical to do so, but assurance of consideration cannot be given except except as to comments received on or before this date.

10 CFR Part 35

Measurement of the Activity of Radiopharmaceutical Dosages

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations on human uses of byproduct material, to require specific medical licensees to (1) Measure the total activity of each radiopharmaceutical dosage, except those containing less than 10 microcuries or a pure beta-emitting radionuclide, before it is administered to a patient; (2) verify that smaller dosages contain less than 10 microcuries; and (3) keep a record of the measurements.

The assary of each radiopharmaceutical dosage before it is administered to a patient is currently required as a condition for a specific license. Measurement of the total activity of radiopharmaceutical dosage helps to protect patients from unnecessary radiation resulting from errors in labeling, calculating or dispensing dosages. The purpose of this rulemaking is:

(1) To simplify licensing by replacing a condition that appears in all medical licenses with one regulation, and

(2) To enhance patient radiation safety by minimizing potential misadministrations caused by not measuring the patient dosage.

DATES: Comment period expires November 30, 1981. Comments received after November 30, 1981 will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

ADDRESSES: Interested persons are invited to submit written comments and suggestions for consideration on the proposed amendment to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch. Comments may also be delivered to Room 1121, 1717 H Street N.W., Washington, DC between 8:15 a.m. and 5:00 p.m. weekdays. Copies of the value/impact analysis, OMB clearance supporting statement, and comments received may be examined at the Commission's Public Document Room at 1717 H Street NW, Washington DC.

FOR FURTHER INFORMATION CONTACT: Elizabeth G. Rodenbeck, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, (Telephone 301-427-4580).

SUPPLEMENTARY INFORMATION:

Background

NRC specific medial licensees are currently required by a license condition to measure the activity of radiopharmaceutical dosages before administering them to patients. The NRC is proposing to change the measurement requirement from a license condition to a regulation that would affect specific licensees. The benefits of changing the license condition to a regulation are the following:

(1) To stress that the measurement is applicable to all specific medical licensees,

(2) To increase the visibility of the measurement requirement, and

(3) To emphasize the importance of the measurement.

The activity of radiopharmaceutical dosages is measured by lowering the syringe, capsule, or vial containing the radioactive drug into an ionization chamber, such as a dose calibrator, and reading the total activity from the display. Measuring the activity before radiopharmaceuticals are administered is important because manufacturers can make mistakes in labeling. In addition, nuclear medicine personnel (technologists, radiopharmacists, or physicians) can make errors in reading labels, calculating dosages or dispensing volumes. These errors could result in unnecessary radiation to patients who could receive either larger dosages than prescribed or additional dosages if the initial dosages were too small. Measurement of the activity of the proposed rule, activities that are under this limit would be verified by placing the dosage in a dose calibrator to assure that the activity is actually less than ten microcuries. This stipulation would help to protect patients from errors made in reading units (for example, millicuries read as microcuries) and calculations incorrect by an order of magnitude (for example, 100 instead of 10). Pure beta-emitting radionuclides, such as phosphorus-32, are exempted from the proposed measurement because of the technical problems associated with their measurement in conventional dose calibrators. Most dosages would be covered by the proposed rule since over 90% of the radiopharmaceuticals administered to patients contain gamma-emitting radionuclides in quantities greater than 10 microcuries.

Description

The proposed rule would apply to all NRC medical licensees who have specific licenses for human use of byproduct material under § 35.11 (which applies to medical institutions) or § 35.12 (which applies to physicians in private practice outside a medical institution). The proposed § 35.15 would require these licensees to measure the total activity of all radiopharmaceutical dosages except those containing a pure beta-emitting radionuclide before administering them to patients. Dosages with activity less than 10 microcuries would be measured only to verify that the activity did not exceed 10 microcuries. The proposed § 35.16 would require licensees to keep a record of the measurements. The record would include the following information: (1) the generic name of the radiopharmaceutical, (2) the total activity at the time of measurement (or a notation that the total activity is less than 10 microcuries), and (3) the date and time of the measurement. Licensees would keep the measurement records for radiopharmaceuticals administered to patients is, therefore, an important quality assurance function that can prevent certain misadministrations.

A few of the radioactive drug dosages used in nuclear medicine may be difficult to quantify accurately in a conventional dose calibrator. For example, the small activity used for vitamin B-12 studies is below the detection sensitivity of some dose calibrators. For this reason, the proposed total activity measurement is limited to activities greater than 10 microcuries. However, as provided for in

1 year as a reasonable demonstration of compliance.

When the licensee has an "in house" nuclear pharmacy under the same license, the measurement and record made by the nuclear pharmacy would fulfill the requirements in §§ 35.15 and 35.16. However, when the licensee obtains radiopharmaceutical dosages from a nuclear pharmacy or drug manufacturer with a separate NRC license, the licensee administering the radiopharmaceutical would make the activity measurement and keep the record required by the proposed §§ 35.15 and 35.16.

Impact

The impact of the measurement requirement on the affected licensees should be minimal since they already measure the activity of radiopharmaceuticals administered to patients as a license condition, and thus have the equipment, personnel, and time to make the measurement. Personnel time required to perform the measurement—place the syringe in the chamber, wait for the readout, and retrieve the syringe from the chamber—is about 15 seconds. Therefore, the proposed rule would require a licensee to spend a total of about 7 hours annually to perform the measurements (derived by multiplying 15 seconds per assay by the average number of nuclear medicine procedures per licensee annually, about 1712, and converting the result into hours). In addition, based on published data, the maximum exposure to the hands of a worker during daily assay operations in a busy nuclear medicine department (12 mR/day) is estimated to be about 0.75 R per calendar quarter. This exposure results in about 4% of the maximum permissible dose per quarter of 18¾ rems to the hands of an individual working in a restricted area as established in § 20.101 of 10 CFR Part 20.

The impact of the recordkeeping requirement on the affected licensees should be minimal since most medical licensees currently maintain records similar to those proposed. The total time required by a licensee to make each record is estimated at about 40 seconds. Multiplying the time per record by the average number of nuclear medicine procedures per licensee (1712) and converting the result into hours yields an annual burden of about 19 hours per licensee to perform the proposed recordkeeping.

Paperwork Reduction Statement

The Paperwork Reduction Act of 1980 (Pub. L. 96–511) requires that this proposed rulemaking be submitted to the Office of Management and Budget for clearance of the recordkeeping requirement contained in it. This clearance procedure has been initiated simultaneously with the publication of this proposed rule in the **Federal Register.** The "Request for Clearance" Supporting Statement and other related documentation submitted to OMB has been placed in the NRC Public Document Room at 1717 H Street, N.W., Washington, D.C. 20555 for inspection or copying for a fee.

Regulatory Flexibility Certification

Based upon the information available at this stage of the rulemaking proceeding and in accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission hereby certifies that, if promulgated, this rule will not have a significant economic impact upon a substantial number of small entities. The proposed rule affects about 2000 specific licenses under 10 CFR 35.11 or 35.12. These licenses are issued principally to medical institutions. Small business entities, primarily physicians in private practice, comprise about 275 of the specific medical licenses. Since the affected licensees currently assay radiopharmaceutical dosages as a license condition, they have the equipment, personnel, time, and expertise to comply with the proposed rule. Although most licensees already maintain similar records, an additional expense might be incurred for the time required to keep the detailed measurement records proposed in the rule. The annual recordkeeping burden imposed by the proposed rule is estimated to be 19 hours for the average licensee.

The potential gains in patient protection significantly outweigh the economic impact on small medical licensees. However, the NRC is seeking comments and suggested modifications because of the widely differing conditions under which small medical licensees operate.

Any small entity subject to this regulation which determines that, because of its size, it is likely to bear a disproportionate adverse economic impact should notify the Commission of this in a comment that indicates:

(a) The licensee's size in terms of annual income or revenue, number of employees and, if the licensee is a treatment center, the number of beds and patients treated annually;

(b) How the proposed regulation would result in a significant economic burden upon the licensee as compared to that on a larger licensee;

(c) How the proposed regulations could be modified to take into account the licensee's differing needs or capabilities;

(d) The benefits that would be gained, or the detriments that would be avoided to the licensee, if the proposed regulations were modified as suggested by the commenter; and

(e) How the regulation, as modified, would still adequately protect the public health and safety.

Under the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and section 553 of title 5 of the United States Code, notice is hereby given that adoption of the following amendments to 10 CFR Part 35 is contemplated.

PART 35—HUMAN USES OF BYPRODUCT MATERIAL

1. Part 35 is amended by adding immediately after § 35.14 a new undesignated centerhead to read as follows:

Special Requirements for Radiopharmaceutical Dosages

2. New §§ 35.15 and 35.16 are added to read as follows:

§ 35.15 Requirement to measure the activity of radiopharmaceutical dosages.

Any liensee authorized under §§ 35.11 or 35.12 for human use of byproduct material shall:

(a) Measure the total activity of each radiopharmaceutical dosage that contains more than 10 microcuries of a radionuclide that emits electromagnetic radiation in the form of gamma rays or X-rays before the dosage is administered to a patient.

(b) Measure to verify that the total activity does not exceed 10 microcuries for each radiopharmaceutical dosage with an activity of 10 microcuries or less.

§ 35.16 Records of measurements.

(a) The licensee shall preserve, for Commission inspection, the records of the measurements required in § 35.15 for 1 year following the date of the measurement.

(b) Records of the measurements made under § 35.15 must contain the:

(1) Generic name of the radiopharmaceutical;

(2) Total activity of the dosage at the time of measurement, or a notation that the total activity is less than 10 microcuries; and

(3) Date and time of the measurement.

(Secs. 81, 161b, and o, Pub. L. 83–703, 68 Stat. 935, 948 (42 U.S.C. 2111, 2201 (b and o)); Sec. 201 as amended, Pub. L. 93–438, 88 Stat. 1242 (42 U.S.C. 5841))

Dated at Bethesda, Maryland, this 12th day of August, 1981.

For the Nuclear Regulatory Commission.

E. Kevin Cornell,

Deputy Executive Director for Operations.

50 FR 15752
Published 4/22/85
Comment period expires 5/22/85

10 CFR Part 35

Physician's Use of Radioactive Drugs

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations to allow physicians to use technetium-99m labeled sulfur colloid for gastroesophageal imaging; technetium-99m labeled sulfur colloid, pertechnetate, and macroaggregated human serum albumin for LeVeen, ventriculo-atrial and ventriculo-peritoneal shunt imaging; and technetium-99m labeled pertechnetate for cystography and dacryocystography. Without this amendment, each NRC licensee that wants to use these radioactive materials in these ways would have to apply to the NRC for permission to do so. The proposed rule will allow physicians or hospitals that are now licensed by NRC to use other similar materials to use these drugs without making an application to NRC.

DATE: Comment period expires May 22, 1985.

Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

ADDRESSES: Send comments to: The Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, ATTN: Docketing and Service Branch. Hand deliver comments to: Room 1121, 1717 H Street NW., Washington, DC between 8:15 am and 5:00 p.m. Examine comments received, environmental and regulatory analyses and the requests for exception at: The NRC Public Document Room 1717 H Street, NW, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Norman L. McElroy, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: (301) 427–4108.

SUPPLEMENTARY INFORMATION: Physicians who want to use certain readioactive materials in the practice of medicine may do so only in accordance with a license issued by the Nuclear Regulatory Commission (NRC) or by States which have an agreement with the NRC to license the use of these materials instead of the NRC.

As new radiopharmaceuticals, radioactive sources, medical devices, and uses of radioisotopes are developed, the NRC considers adding them to one of the groups under which medical licenses are issued. The groups were designed to allow physicians and community hospitals wide access to nuclear medicine services. The groups in § 35.100 contain only radiopharmaceuticals that are the subject of an FDA-approved "New Drug Application" (NDA), or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by FDA. A licensee authorized to use all the materials listed in a group is referred to as a "group medical licensee."

NRC regulations in § 35.14(b)(6) that apply to the group medical licensees provide that when a physician uses byproduct material for clinical procedures other than those approved by FDA and specified in the product labeling or package insert, the physician must follow the product labeling regarding: (1) Chemical and physical form, (2) route of administration, and (3) dosage range. The NRC has received requests to amend its regulations to allow physicians to use technetium-99m labeled sulfur colloid for gastroesophageal imaging; technetium-99m labeled sulfur colloid, pertechnetate, and macroaggregated human serum albumin for LeVeen, ventriculo-atrial, and ventriculo-peritoneal shunt imaging; and technetium-99m labeled pertechnetate for cystography and dacryocystography. These are clinical procedures that are not listed in the product labels.

(As a separate matter, the NRC recently allowed persons who are licensed to use materials in § 35.100 Group II or III to also use pertechnetate for dacryocystography and sulfur colloid for gastroesophageal imaging (see 50 FR 7663, published February 25, 1985). That action was precipitated by a letter to NRC from FDA that said those two methods of use had recently been approved for listing on the respective package inserts, but that some manufacturers might not be able to print new package inserts for several months. The NRC has included those two methods of use in this proposed rulemaking so that the regulation will provide a complete list.)

It is noteworthy that NRC and FDA have sought a solution to the general problem of drug labeling, and FDA currently is considering a program to authorize additional clinical procedures that use approved radiopharmaceuticals. However, until such a program is implemented, NRC believes that this rulemaking is the most appropriate way to resolve the problem in this interim period. This policy was described in an NRC rulemaking published in the **Federal Register** on February 3, 1983 (48 FR 5217).

The requests that NRC received provided a description of the clinical procedure, a justification for why the regulatory action is needed, the purpose of the procedure, an analysis of the radiation dose, and additional technical and scientfic information. (Each of the requests is available for inspection at the NRC Public Document Room, 1717 H Street, NW, Washington, DC.) The NRC has reviewed the requests to determine whether the requested regulatory action might result in an unreasonable risk to the safety of the public or might endanger life or property. The NRC specifically considered two criteria:

- No unjustified dose to the patient, and
- Demonstration of adequacy of occupational radiation protection measures.

With assistance from its Advisory Committee on the Medical Uses of Isotopes (ACMUI), the NRC has determined that the above criteria have been met for the proposed clinical procedures. Many of the committee members believe that these clinical procedures are useful, and the risk/benefit ratio for these procedures is extremely low. They also noted that these techniques will probaby become routine when allowed by NRC.

Technetium-99m labeled sulfur colloid can be administered orally either as a solid or liquid test meal. Following oral administration, technetium-99m sulfur colloid goes from the esophagus to the stomach, small intestine, and the upper large intestine. This clinical procedure permits external imaging which is helpful in assessing gastric emptying, gastroesophageal reflux, and esophageal transit. The gastric emptying procedure is useful in demonstrating the presence and the severity of gastric motor disorder; the gastroesophageal reflux study may demonstrate backward flow in the digestive tract. The esophageal transit study may demonstrate obstructions or abnormal transit time. The normal dosage is 0.3 millcuries. The radiation dose to an average adult patient from 1 millicurie of orally administered technetium-99m sulfur colloid as a liquid is: 0.1 rad to the stomach wall; 0.3 rad to the small intestine; 0.5 rad to the upper large intestine; 0.3 rad to the lower large intestine; 0.1 rad to the ovaries; 0.01 rad to the testes; and 0.02 rad to the whole body. The estimated absorbed radiation dose to an average adult patient from 1 millicurie of orally administered technetium-99m sulfur colloid as a solid food is: 0.2 rad to the stomach wall; 0.2 rad to the small intestine; 0.4 rad to the upper large intestine; 0.3 rad to the lower large intestine; 0.1 rad to the ovaries, 0.004 rad to the tests; and 0.02 rad to the whole body.

These estimated absorbed radiation doses and the following doses are similar to other absorbed doses received from other diagnostic nuclear medicine and x-ray procedures.

A LeVeen shunt is an implanted tube that drains built-up fluid from the peritioneal cavity to a large central vein. Technetium-99m labeled sulfur colloid, pertechnetate, or macroaggregated human serum albumin can be injected into the peritoneal cavity to diagnose shunt malfunction, such as blockage by clot or valve failure, by taking images of the shunt. The normal dosage is 3 to 10 millicuries. The radiation dose from an intraperitoneal injection of a 3 millicurie dosage of technetium-99m sulfur colloid is: 0.02 rad to the whole body; 0.02 rad to the tests; 0.02 rad to the ovaries; 0.03 rad to the liver; 0.02 rad to the spleen and 0.03 rad to the red marrow.

A ventriculo-atrial shunt is a tube implanted in patients with hydrocephalus (fluid build-up in the head). It drains the fluid from the head to the atrial cavity. Technetium-99m labeled colloid, pertechnetate, or macroaggregated human serum albumin is injected into the shunt system of the patient to localize shunt blockage before surgical repair is performed. The normal dosage is 1 to 5 millicuries. The radiation dose from an injection of a 5 millicurie dosage of technetium-99m to a patient with a patent shunt is: 0.1 rad to the whole body and 0.1 rad to the brain.

A ventriculo-peritoneal shunt is an implanted tube in patients with hydrocephalus (fluid build-up in the head). It drains the fluid from the head to the peritoneal cavity. Technetium-99m labeled sulfur colloid, pertechnetate, or macroaggregated human serum albumin is injected into the shunt of patients to localize blockage before performing surgical repairs. The normal dosage is 1 to 5 millicuries. The radiation dose from an injection of a 5 millicurie dosage of technetium-99m to a patient with a patent shunt is: 0.1 rad to the whole body and 0.1 rad to the brain.

Cystography is a procedure for patients with bladder problems. A tube is inserted into the bladder of a patient. Technetium-99m pertechnetate is instilled through the tube into the bladder. Images are taken during filling and voiding of the bladder to measure the amount of reflux (backward flow) into the upper tracts, bladder volume at which reflux occurs, drainage time of reflux after voiding, and the remaining urine volume. The normal dosage is 1 millicurie. The radiation dose from a 1 millicurie dosage of technetium-99m pertechnetate is: 0.002 rad to the whole body, 0.006 rad to gonads, and 0.2 rad to the bladder.

Dacryocystography is a procedure for patients whose eyes exhibit excessive teardrops (epiphora). This procedure is performed to assess tear production and drainage in patients, and for nasolacrimal system imaging. Technetium-99m labeled pertechnetate is administered as a sterile eye drop. The normal dosage is 100 to 250 microcuries. The radiation dose from a dosage of 100 to 150 microcuries of technetium-99m pertechnetate per eye drop to the germinal epithelium of the lens is: 0.01 to 0.02 rad under normal physiological conditions. With blocked lacrimal drainage, the dose to the lens is 0.4 to 0.6 rad.

Finding of No Significant Environmental Impact: Availability

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that this is not a major Federal action significantly affecting the quality of the human environment and therefore an environmental impact statement is not required. The assessment shows that any detectable effect on the environment is unlikely. The environmental assessment and finding of no significant impact on which this determination is based are available for inspection at the NRC Public Document Room, 1717 H Street, NW, Washington, DC. Single copies of the environmental assessment are available from Mr. McElroy (*See* "**FOR FURTHER INFORMATION CONTACT**" heading).

Paperwork Reduction Act Statement

This proposed rule contains no information collection requirements and therefore it is not subject to the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

Regulatory Analysis

The NRC has prepared a draft regulatory analysis for this proposed rule. The analysis examines the costs and benefits of the alternatives considered by the NRC Public Document Room, 1717 H Street, NW, Washington, DC. A single copy may be obtained from Mr. McElroy (*See* "For Further Information Contact" heading).

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the NRC certifies that the rule, if adopted, will not have a significant economic impact on a substantial number of small entities. The NRC has prepared a draft regulatory analysis for this proposed rule that examines the economic impact of this action. The analysis notes that approximately 1900 medical licensees may experience some beneficial impact from the rule. The proposed rule would spare each medical licensee who desires to use the radioactive material in the requested manner the estimated $230 cost of preparing a license amendment request, the $120 amendment fee, and the 60-day delay associated with the amendment of the license.

The Commission is seeking comment particularly from small entities (*i.e.*, small businesses, small organizations, and small jurisdictions as defined by the Regulatory Flexibility Act) about the ways the proposed rule will affect them and the ways it may be modified to impose less stringent requirements on them which will still adequately protect the public health and safety. Those small entities that offer comments on how the regualtions could be modified to take into account their differing needs should specifically discuss:

(a) The size of their business and how the proposed regulations would result in a significant economic burden upon them as compared to larger organizations in the same business community;

(b) How the proposed regulation could be modified to take into account their differing needs or capabilities;

(c) The benefits that would accure, or the detriments that would be avoided, if the proposed regulation were modified as suggested by the commenter;

(d) How the proposed regulation, as modified, would more closely equalize the impact of NRC regulations or create more equal access to the benefits of Federal programs as opposed to providing special advantages to any individuals or groups; and

(e) How the proposed regulation, as modified, would still adequately protect the public health and safety.

List of Subjects in 10 CFR Part 35

Byproduct material, Drugs, Health facilities, Health professions, Incorporation by reference, Medical devices, Nuclear materials, Occupational safety and health, Penalty, Radiation protection, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the following amendment to 10 CFR Part 35 is being considered.

PART 35—HUMAN USES OF BYPRODUCT MATERIAL

1. The authority citation for Part 35 continues to read as follows:

Authority: Secs. 81, 161, 162, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§35.2, 35.14(b), (e) and (f), 35.21(a), 35.22(a), 35.24, and 35.31(b) and (c) are issued under sec. 161(b), 68 Stat. 948, as amended 42 U.S.C. 2201(b); and §§ 35.14(b)(5)(ii), (iii) and (v) and (f)(2), 35.25 and 35.31(d) are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

* * * * *

2. In § 35.14, paragraph (b)(7) is revised to read as follows:

§ 35.14 Specific licenses for certain groups of medical uses of byproduct material.

* * * * *

(b) * * *

(7) The following radiopharmaceuticals, when used for the listed clinical procedures, are not subject to the restrictions in paragraph (b)(6) of this section:

(i) Technetium–99m pentetate as an aerosol for lung function studies;

(ii) Technetium–99m sulfur colloid as a solid or liquid for gastroesophageal imaging;

(iii) Technetium–99m sulfur colloid, pertechnetate, or macroaggregated human serum albumin for LeVeen shunt imaging;

(iv) Technetium–99m sulfur colloid, pertechnetate, or macroaggregated human serum albumin for ventriculo-atrial shunt imaging;

(v) Technetium–99m sulfur colloid, pertechnetate, or macroaggregated human serum albumin for ventriculo-peritioneal shunt imaging;

(vi) Technetium–99m pertechnetate for cystography; and

(vii) Technetium–99m pertechnetate for dacryocystography.

* * * * *

Dated at Bethesda, Maryland this 5th day of April 1985.

For the Nuclear Regulatory Commission.

William J. Dircks,

Executive Director for Operations.

50 FR 30616
Published 7/26/85
Comment period expires 11/18/85

10 CFR Parts 30, 31, 32, 35, and 40

Medical Use of Byproduct Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to revise its regulations to modify the process for licensing and regulating the medical use of radioactive byproduct material. The proposed revision would primarily affect hospitals, clinics, and individual physicians.

By clarifying and consolidating all the essential radiation safety requirements that are now contained in the regulations, license conditions, regulatory guides, and staff positions, the proposed regulation provides a single source of requirements related specifically to medical use of byproduct materials. The proposed regulation also provides flexibility for licensees to update their day-to-day radiation safety procedures. The revision of the regulations would provide a more efficient method for regulating the medical uses of byproduct material.

DATE: Comment period expires November 18, 1985. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments filed on or before this date.

ADDRESSES: Submit written comments and suggestions to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

Copies of the preliminary regulatory analysis and the comments received may be examined at the Commission's Public Document Room at 1717 H Street NW., Washington, DC. Single copies of the preliminary regulatory analysis and environmental impact assessment are available from Norman L. McElroy, Office of Nuclear Material Safety and Safeguard, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: (301) 427–4108.

FOR FURTHER INFORMATION CONTACT: Norman L. McElroy, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: (301) 427–4108.

SUPPLEMENTARY INFORMATION:

ByProduct Material in Medicine

Use for Patient Care

Radioactive materials are used in drugs in the field of nuclear medicine. Drugs labeled with radioisotopes are known as radiopharmaceuticals. In diagnostic nuclear medicine, patients receive these materials by injection, inhalation, or oral administration. Physicians use radiation detection equipment to visualize the distribution of a radioactive drug within the patient. Using this technology, it is possible to locate tumors, assess organ function, or monitor the effectiveness of a treatment. In therapeutic nuclear medicine, larger quantities of radiopharmaceuticals are adminstererd to treat hyperactive thyroid conditions and certain forms of cancer. An estimated 15 to 20 million nuclear medicine procedures are performed in this country annually.

Sealed radioactive sources that produce high radiation fields are used in radiation therapy to treat cancer. A radioactive source in a teletherapy machine can be adjusted to direct a radiation beam to the part of the patient's body to be treated. An estimated 2 million teletherapy treatments are performed annually by NRC licensees. Smaller, less radioactive sealed sources are designed to be implanted directly into a tumor area or applied on the surface of an area to be treated. This procedure is known as brachytherapy. NRC licensees perform approximately 10,000 brachytherapy treatments annually.

Sealed radioactive sources can also be used in machines that are used for diagnostic purposes. The source provides a beam of radiation that is projected through the patient. A device on the other side of the patient detects the amount or spatial distribution of radiation that goes through the patient. This can provide information about tissues within the patient. This is a relatively new development in the field of medicine and the NRC has no estimate of the number of these diagnostic procedures performed annually.

State and Federal Regulation

Twenty-seven states, known, as Agreement States, have assumed responsibility for regulating certain radioactive materials within their respective borders by agreement with the NRC. (This kind of agreement is authorized by the Atomic Energy Act.) They issue licenses for the medical use of byproduct material. In non-Agreement States, the NRC issues licenses to medical institutions (mostly hospitals and clinics) and to individual physicians. These licenses authorizes certain disgnostic and therapeutic uses of radioactive materials.

NRC's Regulatory Program

Policy Regarding the Medical Use of Byproduct Material

In a policy statement published in 1979 (44 FR 8242), the NRC noted that it regulates the medical use of byproduct material as necessary to provide for the radiation safety of workers and the general public, regulates the radiation safety of patients where justified by the risk to patients, and minimizes its intrusion into medical judgments affecting patients, and into other areas traditionally considered to be the practice of medicine. The NRC does have the authority to regulate the medicial use of byproduct material to protect the health and safety of patients, but also recognizes that physicians have the primary responsibility for the protection of their patients. NRC regulations are predicated on the assumption that properly trained and adequately informed physicians will make decisions in the best interest of their patients.

This revision retains NRC's current balance between adequate controls and avoidance of undue interference in medical judgments. Too much regulation could result in poorer health care delivery to patients. Insufficient regulation could result in the unwarranted or unsafe use of radiation.

Current Licensing Practice

The current regulations in 10 CFR Part 35, "Human Uses of Byproduct Material," provide for general and specific licenses for medical use.

The general license in current § 35.31 authorizes physicians to use small quantities of prepackaged, individual dosages of byproduct materials. Physicians simply submit a registration Form NRC–482 to NRC. A validated copy with a registration number is returned to the applicant.

Most medical institutions and physicians who use byproduct material need more byproduct material than can be permitted under the general license program. A specific license, which authorizes a larger inventory of byproduct material and a wider variety of uses, may be issued for one or more of six types of medical use, defined as Groups I–VI in the current § 35.100. Each group is comprised of a number of diagnostic or therapeutic procedures that have been grouped together because they require similar physician training and radiation safety precautions for safe use. A separate specific license may also be issued for use of a teletherapy unit. Applications for a specific license are much more detailed than a general license application and actually contain the applicant's step-by-step radiation safety procedures, which are reviewed and approved individually by NRC.

The NRC has issued 650 general licenses, and in 1983 received seventeen new applications. NRC currently has about 2500 specific medical licensees (2200 hospitals and 300 physicians in private practice). In 1983, the NRC received 143 new applications for specific licenses, 647 license renewal applications, and 1,772 license amendment requests for a total of 2,562 licensing actions.

To help licensees design their radiation safety programs, the NRC has published many NUREG reports and regulatory guides that contain radiation safety guidance. These publications address three general areas: radiological health and safety, personnel training and experience, and facilities and equipment. Experience has shown that if licensees follow the guidance in the publications, the medical use of byproduct material generally poses no hazard to workers and the public.

Problems with Current Practice

The General License. The general license program is based on the fact that the quantities and forms of material that are authorized by a general license present a very low health risk. The NRC believes it is no longer efficient to issue medical general licenses. The tests authorized under § 35.31 have been superseded by newer procedures with greater diagnostic accuracy. These developments have been reflected by a significant decrease in applications for general licenses. As noted above, although NRC has on file 650 in-vivo general licenses under § 35.31, only seventeen new applications were received by NRC in 1983.

To determine the status of general license use, the staff performed a telephone survey of 10 percent of the current registrants. The survey results indicated that less than 9 percent of all the current registrants still use material under a general license; many are now using byproduct material under a specific license. Because of the low level of use of the general license, the NRC has concluded that it no longer serves a useful role in licensing the medical use of byproduct material.

The Specific License. Because of the potential radiation hazard to workers and the public, the specific license program incorporates three regulatory features: case-by-case review of applications, on-site inspections, and periodic license renewals.

A major problem with the current licensing program is that radiation protection requirements are not located in one document. Requirements are scattered in the regulations, Inspection and Enforcement (IE) orders that modify a license or group of licenses, and in conditions attached to individual licenses. Suggestions for good practice are contained in NRC regulatory guides and technical reports (NUREG's). For example, Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Programs," and NUREG–0267, "Principles and Practices for Keeping Occupational Radiation Exposure at Medical Institutions As Low As Reasonably Achievable," contain many recommendations that the NRC believes are important for the safe use of byproduct material. The revision of Part 35 incorporates those recommendations, and also corrects the piecemeal fashion in which the regulations have been amended over the years to address specific problems.

When preparing a specific license application for review under the current licensing program, the applicant must include sufficient information to assure NRC reviewers that byproduct material will be used safely. Applicants include, as an integral part of the application package, copies of their proposed step-by-step radiation safety procedures. In many cases, the procedures are edited versions of procedures described in Regulatory Guide 10.8.

When NRC receives the application, a licensing reviewer evaluates the applicant's training and experience, facility, equipment, and radiation safety procdures in detail. If the application is found to be incomplete or inadequate, a "deficiency letter" is sent to the applicant explaining what additional information is needed. Review of the application is not resumed until a written response from the applicant has been received. Staff studies indicate that about 40 percent of all applicants receive either a deficiency letter or a phone call for additional information. The need for deficiency letters stems from two sources. Guidance on what is needed to get a license is unclear and scattered in various documents. Application review practice must be conservative because the application and license comprise the basis for regulatory control. Deficiency letters are costly for the NRC and the applicant and greatly increase the time needed to complete licensing actions.

When the application, including any additional submitted information, is approved, the NRC issues a specific license that grants the authority for medical use of byproduct material in accordance with the program described in the application. Requirements in addition to those contained in the regulations are frequently incorporated in the license as conditions of use. Since the licensee must comply with conditions specified in the license, the license, rather than the regulations, is frequently used to regulate radiation safety in the day-to-day use of byproduct material.

The specific license is valid for five years. The license must be amended before methods of use or procedures may be added or changed, or before permitting additional physicians to use materials. Amendments to a specific license involve an application, review, and approval process similar to that for new licenses. Renewals are treated in the same manner as new license applications.

This regulatory process was appropriate during the evolution of the use of byproduct material in medicine. Radiation safety problems were not well defined, regulatory requirements had not caught up with developing technology, physician training curricula had not been established, and there were no formal training programs for nuclear medicine technologists. Therefore, it was necessary to regulate by reviewing each individual radiation safety program to ensure that the applicant had adequate personnel, facilities, and equipment.

Proposed Revision of the Regulatory Program

Overview

NRC intends to modify its regulation of the medical use of byproduct material. The Commission plans to revise the regulations to provide a single source of requirements specifically related to medical use of byproduct materials, and within the boundaries set by the regulations, allow medical licensees to modify their radiation safety procedures, facilities, and equipment,so they can make prompt use of new safety methods and also meet new needs caused by changes in demand for various patient care services or in patient load. The proposed revision of 10 CFR Part 35 is consistent with the Commission's general policy on medical use of byproduct material issued February 9, 1979 (44 FR 8242). It states "NRC will continue to regulate the medical uses of radioisotopes, as necessary, to provide for the radiation safety of workers and the general public."

Codification of Requirements in the Regulations

NRC proposes to simplify regulation of medical licensees by incorporating all medical use requirements in 10 CFR Part 35. These regulations would become the primary means of regulating the medical use of byproduct material. General safety requirements for worker instruction, worker safety, noncompliance reports, and materials licensing that are in Parts 19, 20, 21, and 30 will also continue to apply to Part 35 licensees. The current license application process will be unchanged. The applicant prepares a complete Form NRC–313. That form asks for the following information: the name and mailing address of the applicant; the location of use; a person who can be contacted about the application; what materials are requested; the purpose (in this case, "medical use"); the training and experience of the authorized users and Radiation Safety Officer; the worker radiation safety training program; facilities and equipment; the radiation safety program; and waste management. Licensees would not face significant new regulatory burdens because, in most cases, these requirements are currently imposed as license conditions. Under the proposed revision, the license would authorize medical use of byproduct materials for specified types of use. A licensee's day-to-day uses would be controlled by the regulations. This would simplify inspections for NRC because inspectors would only need to be familiar with one set of regulations rather than a different set of license conditions and radiation safety procedures at each facility.

License Application, Issuance, and Authority and Responsibility

New revisions of Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Programs," and Draft Regulatory Guide TM 608–4, "Guide for the Preparation of Licenses in Medical Teletherapy Programs," will contain instructions on the type and extent of information that must be submitted based on what byproduct materials the applicant has requested. They will also contain model procedures that the applicant can use to develop site-specific procedures. (Consistent with current practice, applicants will alternatively be allowed to simply certify that they will follow the model procedure developed by NRC staff with public comment and published in a regulatory guide to meet a certain requirement. This method significantly reduces the amount of time NRC must spend reviewing procedures.) The applicant mails the completed application, with application fee, to the NRC office identified on the form.

The NRC staff will continue to review the application to determine whether the applicant's radiation safety program is sufficient to meet the requirements of the regulations. After completing the review, if the applicant's program appears incomplete or inadequate, NRC will issue a deficiency letter that describes the apparent shortcomings in the applicant's program and requests clarification or correction. If the applicant's response to the deficiency letter is satisfactory (or if no deficiency letter was needed), the license will be issued.

Licensees will be free to modify their procedures after conducting a required internal review and approval process. At medical institutions, the Radiation Safety Committee would review and approve a modified procedure before it could be implemented. At non-institution facilities, the Radiation Safety Officer (RSO) and management would review and approve changes. This will allow each licensee to make prompt use of new safety methods and to adjust radiation safety procedures to meet new needs caused by changes in demand for patient care services or patient load. A list of radiation safety topics that should be considered when reviewing proposed changes will be published as an appendix in Regulatory Guide 10.8. The right to modify procedures does not relieve the licensee from the requirement to comply with the regulations. This regulatory scheme would *not* incorporate the current requirement that licensees use byproduct material in accordance with the statements made in the application.

This proposed regulatory program, which gives more discretionary authority, and concomitant responsibility, to the licensee, represents a change in the policy that has guided NRC's regulation of medical licensees for several years. The NRC particularly invites comment on whether this change is appropriate at this time, and whether or not it will benefit licensees, workers, and the public.

The proposed regulations require specific training and experience for the use of material in each use group. Proposed authorized user physicians and qualified teletherapy calibration experts (identified in current Part 35 as qualified experts) will have to submit summaries of their training and experience. This is currently required for authorized users and Radiation Safety Officers, but would be a new requirement for qualified teletherapy calibration experts, whose credentials are currently reviewed by the licensee. The staff will review those individuals' training and experience against the standards in the regulation before authorizing them to work under the license. (Also consistent with current practice, any individual who does not meet the standards may ask for an exemption from the training and experience requirements. The NRC staff will review the individual's training and experience with the assistance of its Advisory Committee on the Medical Use of Isotopes, and may issue the exemption as a license condition.)

Enforcement

Under this regulatory scheme, a licensee will be cited for failure to meet the requirements of the regulations or license conditions (which would list, for example, authorized users, locations of use, authorized methods of use, authorized byproduct material and inventory limits, and other site-specific limitations), failure to have on hand the written procedures required by the regulations, failure to follow the procedures on hand, failure to have the records required by the regulations, or failure to follow technically valid procedures (examples: Using an instrument that doesn't work, not determining instrument detection efficiency, not allowing an instrument enough time to respond, or making unsubstantiated assumptions in calculations). Use of material can be authorized either by license or by virtue of working under supervision; use without authorization would be a violation of the regulations and the Act, which would subject the user to an enforcement action.

Amendments

As mentioned above, under the current regulatory scheme, the licensee is required to handle material exactly according to the radiation safety procedures submitted with the application. The NRC frequently receives requests for permission to modify day-to-day radiation safety procedures. Because the regulations will now contain sufficient prescriptive and performance criteria on which to base enforcement actions, the NRC would allow a licensee to change its radiation safety procedures without preparing a formal amendment request, paying an amendment fee, and awaiting NRC approval. This would *not* relieve the licensee from the regulatory requirement to comply with the regulations in Part 35 or in other parts of 10 CFR Chapter I.

Four types of program changes will still require formal license amendments:

(1) *New users.* The NRC will review the training and experience of each proposed authorized user, Radiation Safety Officer, and qualified teletherapy calibration expert as described above before listing the individual on a license.

(2) *New type of use.* A licensee's request to add a type of use (for example, adding radiopharmaceutical therapy to a license that authorizes radiopharmaceuticals for imaging) to an existing license will be handled as a new application. The authorized user's training and experience will be reviewed for adequacy with respect to the new type of use, and procedures that must be submitted in support of the request will be reviewed for completeness and adequacy with respect to the new type of use before the amendment is issued.

(3) *New method of use.* Two developments may occur but only one type of license amendment will be needed:

(a) If a new radioactive material becomes available, and the radiation safety procedures needed for its safe use are identical to the procedures already established for an already established and authorized use (for example, a new imaging agent administered by intravenous injection), no license amendment will be required. Instead, the new material will be added by rulemaking to the list of materials in the appropriate use group specified in the regulations. The NRC will mail to licensees a notice that says those who are authorized to use material in that group may begin using the new material on the effective date of the final rule that adds the new material to the regulations.

(b) If a new radioactive material becomes available but its safe use depends on following a new procedure that current licensees have not submitted and NRC has not reviewed, two actions will be taken.

(i) The new material will be added by rulemaking to the appropriate use group in the regulations but authorization to use it will be limited to persons who were licensed after it was added to the use group and who have submitted the new procedure for review in their application packages.

(ii) NRC will mail to current licensees a notice that says they may apply for authorization to use the new material. With that notice, NRC will also supply a model procedure, which would become a new appendix in Regulatory Guide 10.8, for the new material. Those licensees who want to use the new material will have to submit a request for amendment which includes a proposed procedure that will be reviewed by NRC for completeness and adequacy.

(4) *New location of use.* Two types of amendment may be needed:

(a) A request to leave one location of use and begin working in a new location, for example when moving a private practice to a new office or when moving into a new hospital building, will have to be supported by a complete new application package.

(b) Some licensees receive packages, prepare radiopharmaceuticals, and package waste at a central facility, but actually use the byproduct material at satellite locations. This might be a mobile nuclear medicine service that provides diagnostic services at clients' facilities such as clinics, small hospitals, or nursing homes, or it may be a licensee that has a principal facility and outlying clinics. If the licensee has been approved to offer service at satellite locations, a request to add another satellite location will only have to identify the new location. (Due to the training, space, and equipment commitments needed for safety during therapy procedures, the NRC will generally not authorize licensees to perform therapies at satellite locations. This type of request will be handled on a case-by-case basis.)

Renewals

The NRC license is valid for five years. If a person wants to continue using byproduct material the license must be renewed. The renewal application must completely describe the entire radiation safety program just as a new application does. If a previously submitted radiation safety procedure, facility description, or equipment list still accurately reflects that part of the licensee's program, the renewal applicant may simply make a clear reference to the previous submission. If the licensee has changed a procedure, is using different areas of use, or is using different equipment, a complete new description of the particular procedure, area of use, or equipment must be submitted. The licensee may also take this opportunity to identify new authorized users or request authorization for new types or methods of use.

Summary of Changes Proposed in the Regulatory Program

In summary, the regulation will be amended to require that licensees meet standards that are currently imposed by license conditions. The NRC will continue to review user training and experience. The NRC will review site-specific radiation safety procedures for completeness and adequacy and issue deficiency letters if necessary, but will allow licensees to change procedures that were submitted in support of the application after conducting an internal radiation safety review of each change. However, the right to change procedures does not relieve the licensee from the requirement to comply with the regulations. Amendment requests will generally be reviewed just as new applications are reviewed, but they may incorporate by reference the original application and any previous amendments.

Notes

Word Usage

In preparing the proposed revision of Part 35, one goal was to remove language that might be misinterpreted. The following words used in the revision may require clarification.

1. *Licensee.* The person (individual, partnership, corporation, or agency) listed on the license as the "licensee" is responsible for compliance with regulations and license conditions. The licensee may effect compliance through full-time or part-time employees, contracts with consultants or service organizations, or other business arrangements. The word "licensee" is used throughout the regulation to stress the fact that, no matter which method is used, the licensee is legally responsible in case of non-compliance.

2. *Type of use* and *group.* In the current Part 35 there are six "groups" of use described in § 35.100. Each group is comprised of a set of medical procedures that require similar training and equipment for radiation safety purposes. The word "group" has not been used in the proposed revision in order to avoid confusion between the old and new Part 35. The revision uses the phrase "type of use" for this concept. Some types of use are amalgamations of old groups, and some types are new. The six types of use are: (1) Uptake, dilution, and excretion—Subpart D; (2) imaging and localization—Subpart E; (3) radiopharmaceutical therapy—Subpart F; (4) brachytherapy—Subpart G; (5) sealed sources for diagnosis—Subpart H; and (6) teletherapy—Subpart I.

3. *Method of use* and *procedure.* The word "procedure" is frequently used in supporting documentation for by product materials programs. Sometimes it refers to a specific set of steps that must be taken to effect an end, for example a procedure for ordering and

receiving packages. Sometimes it is used to indicate a type of medical examination or treatment, for example a thyroid uptake study or a cesium implant therapy, without indicating the amount of byproduct material used or the specific steps taken in handling it. The word may also be used to indicate the number of patients cared for over a period of time, for example an average workload of fifteen procedures each day. In order to avoid confusion, the phrase "method of use" appears in the proposed revision. Each type of use is comprised of several methods of use. Each method of use should identify, explicitly or by context, the radionuclide, its chemical and physical form, method of administration, and purpose (diagnosis or therapy).

4. *Dose* and *dosage*. In pharmacy, the word "dose" is used to indicate the amount of chemical administered; in radiation biology it is used to indicate the amount of ionizing energy absorbed per unit mass; and in radiation safety it is used as a shorthand term to indicate a worker's exposure to radiation. In order to avoid confusion, the word "dosage" is used in the proposed revision to indicate quantities of radioactivity that are measured with the base unit Curie. The word dose is used to indicate quantities of radiation absorbed dose or dose equivalent that are measured with the base unit rad or rem.

5. *Record* and *report*. A record is a user-retrievable notation or complete document. It may consist of something as small as a check-mark on a form or something as extensive as a survey of a newly installed teletherapy unit with appended calculations to demonstrate compliance with the limits on exposure in uncontrolled areas. A report is a transfer of information which might be made face to face, by telephone, telegram, computer link, or hard copy transmittal.

6. *Test* and *check*. For many pieces of equipment, drafting committees comprised of industry experts have prepared standards of performance and complete calibration protocols. If a piece of equipment is subjected to the protocol in the calibration laboratory and meets all the standards, then the ability of the equipment to perform as expected in normal field use is assured. In the proposed revision this concept of complete examination is referred to as a "test." During field use it is common practice to subject a piece of equipment to a quick examination to determine whether it is working. This procedure does not examine all parameters of equipment performance. In the proposed revision this concept of perfunctory examination is referred to as a "check."

7. *Location of use, facility*, and *area of use*. The phrase "location of use" is used to describe the building or buildings (typically identified by a single street address) where byproduct material is used. The word "facility" connotes a room or contiguous rooms where byproduct material is used, such as a nuclear medicine clinic comprised of an office, an imaging room, and a dosage preparation and waste storage room. The phrase "area of use" connotes the space used by worker when performing a specific task connected with receiving, handling, or storing byproduct material.

8. *Chemical form*. The current regulation requires that if a radiopharmaceutical is used for indications other than those described in the package insert, the user must nevertheless follow instructions on chemical and physical form, dosage, and route of administration. The proposed revision has deleted the word chemical in its restatement of this requirement because to change the chemical form would be to create a radiopharmaceutical other than the one received from the authorized distributor. Deletion of this word in the proposed revision does not authorize Part 35 licensees to manufacture radiopharmaceuticals.

9. *Available for use*. In many cases the regulation states an equipment possession requirement because the piece of equipment is considered by experts to be an integral part of the radiation safety program. In a few cases the need for a piece of equipment is sporadic and normally scheduled weeks in advance. For example, a licensee who has a diagnostic sealed source in a device (see § 35.500) usually only needs a survey instrument when receiving or returning a radioactive source; there is no need to have the instrument on hand every day. The phrase "available for use" is intended to connote that the licensee either may possess equipment or contract for measurement services, but is not required to have regular day-to-day possession of the described equipment.

10. *Dedicated check source*. A long-lived radioactive source can be used to check the day-to-day constancy of an instrument. The *same* source (a "dedicated" source) must be used every day so that the user knows what reading to expect from the instrument. The source may also be used for other purposes.

11. *Operable*. The word "operable" is not used in the proposed regulation because every piece of equipment must be operable. If a piece of equipment is not operable or reliable, whether due to old or absent batteries, incomplete or improper maintenance, damage, inappropriate use, or improper use, it cannot be used to meet a regulatory requirement because there is no assurance that it accomplished the task for which it was used.

12. *Implement*. This verb is used with its ordinary definition, which is "to carry out, accomplish, or ensure fulfillment of."

13. *Promptly*. This word is used with its ordinary definition, which is "performed readily or immediately."

Record Retention

The Commission requires that licensees make and retain records as evidence of compliance with regulations and license conditions. A review of records during inspections is the least burdensome way that the Commission may be assured that the licensee has developed and implemented a radiation safety program. However, permanent retention of all required records, or retention between inspections, would be unreasonable and would run counter to recent guidance to regulatory agencies that was issued by the Office of Management and Budget. Therefore the Commission has, in the proposed revision, generally adhered to the following policy.

1. For recurring records that are created on a daily basis, for example end-of-day surveys, and for most non-recurring, sporadic, or periodic records, such as individual patient dosage measurements or survey instrument calibrations, the Commission has made a judgment that records retention for two years provides adequate evidence of compliance with requirements.

2. In a few cases a record is only created once or the Commission considers the record to be essential evidence of compliance with regulations that, if not followed, might cause an immediate discernible impact on a worker or member of the public (for example, requirements for the geometry test for a dose calibrator and the teletherapy dosimetry equipment calibration, respectively). In those cases the Commission has made a judgment that retention for the duration of use of the equipment or of the license is necessary.

Effect on Broad Licensees

In addition to the more common "group" licenses which the NRC issues that authorize by product material for uses described in the groups, the NRC has also issued about 100 broad licenses under Part 33 that include medical use. They are issued to large medical/academic institutions that have had several years experience using radioactive materials.

About 50 of the medical use broad licenses that have been issued vest in each institution's Radiation Safety Committee the authority to permit medical practitioners to use byproduct material for both patient care and medical research, to permit individuals to use byproduct material for research in test tubes and animals, and to review the facilities and radiation safety procedures that these individuals will use. Before NRC issues a broad license it reviews the applicant's administrative and safety procedures, the training and experience of the Radiation Safety Officer and of each individual member of the Committee, and the standards and management procedures it will use when reviewing permit requests. This type of license is needed to allow for the orderly evolution of the medical sciences. The NRC will continue to review Committee member qualifications on a case-by-case basis because the size and individuality of each broad license program precludes the preparation of generic prescriptive qualifications. These licensees would be required to comply with the proposed prescriptive and performance criteria of Part 35, but would be exempted from the training and experience requirements of Subpart J and the authorized materials and authorized use restrictions in proposed §§ 35.49, 35.100, 35.200, 35.300, 35.400, and 35.500.

The other 50 medical broad licenses that have been issued are similar to the license described above, except that the Committee only has the authority to permit individuals to use material in test tube and animal research, and only authorizes medical use in accordance with the groups in current § 35.100. The NRC would continue to review the training and experience of medical practitioners before allowing them to use material for medical use. Because control of medical use in these cases is the same as that exercised over the more common group licensees, the basis for a determination of compliance will be the same as that described below for group licensees.

Because, whether at a group or broad license facility, teletherapy is separately licensed "for treatment of humans" and because the NRC reviews qualifications of proposed users and safety procedures, no significant inconsistencies with current teletherapy programs or new teletherapy programs are expected.

Transition Policy for General Licensees

The general license in current § 35.31 has been eliminated from the proposed regulations. In the future, all medical use will be specifically licensed. Current general licensees, all of whom are physicians, will receive a specific license that will be incorporated into NRC's filing system for keeping track of specific licensees. However, they will be limited to the methods of use described in the current § 35.31, and relieved, by license condition on a pre-printed license, from the requirements that are more burdensome than the current general licensee requirements. The only action general licensees will need to take is to respond affirmatively to an NRC notice that asks if they want to continue to have an NRC license that is limited to the methods of use authorized by the current general license.

The Commission proposes, under § 170.11(b), to continue to exempt these licensees from application and renewal fees as long as their programs are limited to the material uses described in current § 35.31. Under the new specific licensing system, former general licensees that want to make any changes in their programs, amend their licenses, or transfer them to other physicians, will have to apply under the new licensing scheme and will be subject to all the fees that apply to other specific licensees.

The Commission proposes to waive fees to former general licensees for the following reasons. General licensees do not now pay fees. About 90% of the 600 or so general licensees are inactive. Each year NRC receives only a very few requests for general licenses under § 35.31. There would be no NRC review time needed and only a minor NRC administrative cost to process these licenses. It would be unfair to charge these licensees the fees listed in 10 CFR Part 170, and it would be more costly for NRC to alter that fee structure than to grant the exemption.

The current Part 35 also grants a general license for in vitro work described in § 31.11 to group licensees without requiring that they submit an in vitro registration form. Under the proposed regulation, applicants would have to specifically request this authorization as a line item on their applications. Part 31 will be amended to continue the in vitro authorization for current medical licensees until their licenses are renewed. In either case, the use of § 31.11 materials within the inventory limits of that section will only be subject to the requirements of § 31.11.

Transition Policy for Specific Licensees

Under the current regulatory program, the license document with the appended application is used to regulate each individual licensee. Because the requirements in the proposed revision were taken from commonly used topical license conditions and regulatory guidance that most licensees have incorporated into their applications, the Commission does not expect any significant inconsistencies between current licensee radiation safety programs and radiation safety programs of applicants that apply after the effective date of the propsed regulations. Therefore, current licensees will normally be cited if they do not comply with the new regulations. However, because each current licensee's radiation safety program was reviewed individually and license conditions were tailored to meet the licensee's individual needs, there may be an occasional inconsistency between a license condition and the regulation (for example, a license may require survey instrument calibration biennially, but the proposed regulation would require calibration annually). There is no health and safety reason to undo these licenses to effect compliance with the regulation. To impose the regulation in addition to or in lieu of the license conditions would not provide for significant additional health and safety. The Commission therefore proposes to resolve possible temporary inconsistencies between license conditions and the regulation by providing in the regulation a transition period between the effective date of the final rule and the expiration date of each license. During this transition period, if there is an inconsistency between a provision in a license (issued prior to the regulation) and the regulation, the proposed regulation states that the license condition would take precedence over the regulation. Because the license conditions were reviewed from the perspective of overall safety and approved by the NRC, the inconsistency would not result in an increased risk to workers or the public.

In addition to the topical license conditions mentioned above (for example, sealed source leak test requirements, special bioassay requirements, radioactive patient surveys and release limits, or waste disposal restrictions), each specific license has an encompassing license condition that requires each licensee to possess and use licensed material in accordance with the statements, representations, and procedures contained in the license application and in letters of clarification. Despite this encompassing condition, licensees would be allowed to make changes in their radiation safety programs; permissible changes would be restricted to those identified in § 35.36, and the licensee would have to conduct the internal review required by that section.

In the case of record retention, the regulation will generally take precedence because, in the past, the Commission has not offered much guidance on this topic. Many applicants have either not specified a period of retention or have incorporated a single, all encompassing record retention phrase "until the Commission authorizes their disposal," rather than shouldering the burden of justifying to NRC a shorter period. If a record is substantively the same as a record described in the proposed regulation and the licensee has not stated a retention period for that specific record, licensees could adopt the retention period stated in the final rulemaking. However, licensees would still have to comply with any record retention period required by a topical license condition or another Part (for example Part 20) of the regulations. (For example, surveys that provide the basis for occupational dose records or measurements of effluent release are governed by Part 20.)

NRC does not currently review qualified teletherapy calibration expert credentials, and does not identify the Radiation Safety Officer on the license. Under this proposal, NRC would begin to review their credentials and identify both of them just as it does now for authorized users. To add current licensees to this new scheme, licensees would be required to submit their credentials for review and approval when the next amendment or renewal request is required. These individuals would be identified on the next license amendment.

The NRC particularly requests public comment on this transition policy and would like to know if licensees envision problems of interpretation or compliance that the staff might not foresee.

Discussion of Proposed Regulations

The primary purpose in initiating this revision to the regulations is to simplify the regulatory process by providing licensees with a single source of requirements for the medical use of byproduct material. Radiation protection standards now contained in several existing regulations, Inspection and Enforcement orders that modify a single license or group of licenses, technical reports (NUREGs), standard conditions of licenses, and regulatory guides would be consolidated into a concise set of regulations. The requirements that apply to all licensees appear first, followed by the specific requirements for each of the six basic types of use.

In the proposed regulation, items of general information, general administrative requirements, and general technical requirements are addressed first in Subparts A through C, respectively. Subparts D through I contain the additional technical requirements that apply to licensees for each of the six new types of use. Subpart J lists the training and experience requirements, and Subpart K lists the penalties for violations of the regulations.

In order to maintain consistency among the various parts of NRC's regulations, conforming amendments have been made to the affected sections of Parts 30, 31, 32, and 40. These conforming amendments can be found immediately after the revised Part 35. A section-by-section discussion of the proposed revision of Part 35 follows.

Title

The title of Part 35 has been changed from "Human Uses of Byproduct Material" to "Medical Use of Byproduct Material" to better reflect the scope of the part.

Authority

This listing provides notice of the statutory basis for the regulations. It also provides notice that the NRC may initiate criminal prosecution of persons who knowingly and willfully do not comply with the prescriptive requirements issued under section 161b or the recordkeeping and reporting requirements issued under section 161o.

Subpart A—General Information

Section 35.1 Purpose and scope.

The regulations in this part apply to all persons licensed by the Commission to intentionally administer byproduct material or the radiation from byproduct material to humans, and to individuals working under their supervision.

Section 35.2 License required.

This section requires that persons have a license issued by the Commission or an Agreement State before they handle byproduct material for medical use. The Commission uses the specific licensing process to limit the use of byproduct material to persons who have the equipment, facilities, training, and experience needed to ensure its safe use. Individuals who are working under the supervision of an authorized user do not need a license document, but this does not relieve them of the requirement to conduct their work in accordance with requirements of the license and the regulations of this chapter. The licensee remains responsible for the noncompliance of such agents or employees, and may be subject to sanctions for their failure to comply.

Section 35.8 Information collection requirements: OMB Approval.

This section provides notice that the Office of Management and Budget has reviewed and approved the information collection requirements contained in this part.

Section 35.15 Definitions.

The term "Agreement State" applies to those states that have entered into an agreement with NRC to assume responsibility for regulating the use of byproduct material within their borders.

The word "ALARA" was added ton identify the acronym for the phrase "as low as reasonably achievable."

The term "area of use" was added to identify a place in which byproduct materials are received, used, or stored. The term is used in § 35.36 to authorize licensees to use byproduct materials in rooms, suites, or building wings not identified in the application.

The term "authorized user" was added to identify individuals who are identified by name on a license and who are authorized by the Commission or an Agreement State to administer byproduct material, or the radiation therefrom, to humans for medical care, and supervise its use by others.

The term "dentist" ws added to identify a group of practitioners licensed by the States who might use byproduct materials in their practice.

The term "medical use" was included to help identify the scope of this part. The word "intentional" was included in the definition to make it clear that occupational and nonoccupational exposures under the regulations of Part 20, accidental exposures, and unwanted exposures from other sources of radiation (e.g., nuclear powered cardiac pacemakers, smoke detectors, and radioactive waste) are not considered medical use. The phrase "in the practice of medicine in accordance with a license" was included to make it clear that NRC recognizes that States may have different difinitions of medical practice or different levels of control and that licensees should not interpret that NRC license as a pre-emption of State medical regulations or an attempt to direct the States' regulation of medical practice.

The word "medical institution" was added to identify organizations in which the radiation safety program depends on the cooperation of individuals from several different departments.

The word "management" was added to identify the individual responsible for defining the licensee's policies and allocating personnel, budget, and space resources.

The word "misadministration" was included to define those instances in which a mistake has been made in the medical use of byproduct material. The definitions are the same as those in the current § 35.41.

The term "mobile nuclear medicine service" was added to describe the transport of byproduct material for the purpose of offering diagnostic nuclear medicine services at addresses other than the principal business address of the licensee.

The word "output" was added to describe the amount of radiation in a teletherapy beam.

The word "physician" was included to identify individuals licensed by the States to practice medicine and therefore eligible to use byproduct meterial in the practice of medicine.

The word "podiatrist" was added to identify a group of practitioners licensed by the States who might use byproduct materials in their practice.

The term "qualified teletherapy calibration expert" was included to replace the term "qualified expert" which is used in the current § 35.24. The new term better reflects the training, experience, and responsibilities of the individual who is responsible for calibrating a licensee's teletherapy unit.

The term "Radiation Safety Officer" was added to identify the individual named on a license and who is responsible for managing the licensee's radiation safety program.

The term "sealed source" was included to identify byproduct material that is specially encapsulated to prevent leakage or escape during use and storage. It is the same definition as use in § 30.4.

The term "visiting authorized user" was added to identify individuals listed as authorized users on one license who, while working for another licensee on a temporary or occasional basis, use byproduct material under the restrictions of the temporary employer's license, which does not identify the visitor as an authorized user. This authorization is based on a frequently used topical license condition.

Section 35.16 Application for license, amendment, or renewal.

At an institution, only management may apply for a license; individual physicians would be listed on that license as authorized users. An individual physician may not apply for use within a medical institution (an organization that provides various medical services). This requirement reflects the need for coordination with other employees who may not be under the administrative control of the authorized user. For use sited outside a medical institution, such as for private practice or mobile service, any person may apply. An application must be filed on Form NRC-313 because it elicits information in an orderly manner that will allow for uniformity in application review procedures.

Teletherapy applications must be submitted separately because the scope and nature of information needed is much different than that needed for the other types of medical use. This requirement does *not* imply that the applicant should have two separate safety programs.

This section also reflects the Commission's decision to delegate to Regional Administrators some licensing functions which, until recently, were conducted in the headquarters. This program was described in **Federal Register** notices published May 27, 1982 (47 FR 23138), April 14, 1983 (48 FR 16030), May 9, 1984 (49 FR 19630), and April 15, 1965 (50 FR 14692).

Section 35.17 License amendments.

The Commission requires that the licensee obtain an amendment for any changes in the byproduct material program that might increase the potential for radiation exposure to workers and the general public, or make it difficult for the Commission to conduct its inspection program. The Commission has determined that certain changes are potentially significant for the following reasons and thus will require an amendment:

(1) The NRC must be assured that the licensee has adequate training and experience and facilities before authorizing a change in the type or method of medical use or amount of byproduct material used. Such a change might also indicate a need for increased inspection frequency.

(2) The use of byproduct material at an address not identified on the license would make it impossible for the Commission to make unannounced inspections. The Commission relies on the unannounced inspection to assure day-to-day compliance. For the purpose of this part, the phrase "location of use" refers to a building. (Moving from one room to another within a building would not constitute a change in location of use.)

(3) The Commission must be assured that the training and experience of Radiation Safety Officers, authorized users, and qualified teletherapy calibration experts is sufficient to assure that they are able to understand and follow regulations for the safe use of byproduct material.

Section 35.18 Notifications.

A notification requirement was added to require the licensee to notify the Commission if an authorized user, Radiation Safety Officer or qualified teletherapy calibration expert is no longer affiliated with the licensee's byproduct material program. Without this notice the NRC would not have assurance that the collective training and experience of the licensee's remaining personnel is adequate to ensure the safe use of byproduct material for all the types of use authorized by the license. The Commission has made a judgment that notification within 30 days is sufficient because technicians who have worked under the supervision of the authorized user can adequately ensure the safe receipt and proper storage of byproduct material. However, absence of an individual to oversee a byproduct material program may increase the probability of an accumulation of unused byproduct material or unauthorized use of material. This presents an unacceptable potential hazard.

Section 35.28 License issuance.

The Commission has selected a license term of five years. A shorter term would not benefit the public health and safety because past experience indicates that medical programs do not generally change significantly over that period of time. A shorter term may unduly interfere in patient care because the licensee would spend an inordinate amount of time requesting renewals. A longer term may occasionally result in unintentional abandonment of the license.

The applicant must use Form NRC-313 to provide for an orderly safety review of the applicant's program. The Commission will apply certain standards when reviewing an application so as to ensure that the safety of workers and the public will not be compromised if the license is granted. The staff must be assured that the applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property (§ 30.33(a)(2)), and that the authorized users are qualified by training and experience to use the material for the purposes listed in the application in such a manner as to protect health and minimize danger to life or property (§ 30.33(a)(3)), and that applicant has established procedures adequate to assure that safe use of byproduct material.

Concerning fees. Congress has directed that agency services, such as licensing and inspection, must be self-sustaining to the extent possible.

Section 35.29 Specific exemptions.

As part of an application or amendment request, a person may request an exemption from any requirement of this part. The NRC occasionally receives requests for exemptions from procedural, equipment, or training standards. The Commission may allow the exemption if the applicant can show that it will not compromise the health and safety of workers and the public.

Subpart B—General Administrative Requirements

Section 35.30 ALARA program.

An ALARA program is a management tool needed to assure that all reasonable efforts are made to assure that safe use of byproduct material. (See 'Management Organization and Administration for ALARA' by Kathren, *Health Physics*, Vol. 42, No. 2, February 1982, p. 119–131, and 'Radiation Safety in a Nuclear Medicine Department,' by Gandsman et al., *Health Physics*, Vol. 38, No. 3, March 1980, p. 399–408.) In an institution many workers from different departments might be occasionally exposed to byproduct material. The Commission has made a judgment that a formal ALARA program is the only management tool that can ensure a cooperative effort to reduce individual and collective dose and ensure regular safety reviews. Specific requirements usually considered part of an ALARA program are required by §§ 35.31 amd 35.32.

The annual briefing of management by the Radiation Safety Officer on the byproduct material program is intended to assure that licensee management knows what kinds of byproduct material are used in which departments, which workers are involved, its use, the regulatory requirements that govern its use, and current and potential radiation safety problems. Management needs this information to ensure that its decisions do not inadvertently result in activities contrary to the regulations or license conditions.

In this proposed rulemaking the Commission has not required non-institutional licensees, such as one or a few physicians in private practice, to have a formal ALARA program because, for those licensees, the physician authorized user is usually also the Radiation Safety Officer, management, and the line manager. Hence, any formal ALARA report requirement would consist of the physician reporting to himself. However, the Commission would appreciate comments as to whether *all* medical licensees should have a formal ALARA program. If so, should small licensees conduct an internal annual review or should that review be conducted by someone who is not associated with the licensee's program on a day-to-day basis? Commenters are reminded that the exhortation in 10 CFR 20.1(c) to make every reasonable effort to maintain radiation exposures and releases of radioactive materials ALARA applies to medical licensees.

Section 35.31 Radiation Safety Officer.

The Radiation Safety Officer is an individual with special expertise who is needed to coordinate the safe use of byproduct material in accordance with the license and the Commission's regulations.

Section 35.32 Radiation Safety Committee.

The proposed Part 35 requires institutional licensees to establish a Radiation Safety Committee to oversee the use of byproduct material. The committee is required because, in an institution, radiation safety for *all* workers (users and ancillary staff) and the public depends on the cooperation of employees from administratively separate departments. Without the benefit of committee discussion, authorized users may not be aware of radiation safety problems outside their own department that are caused by their patients, packages, or waste. The Committee's deliberations will provide management and authorized users with information that is needed to optimize allocation of resources available for radiation safety. A Committee is not required for licensees that are not medical institutions because such organizations generally do not have the multi-armed, multi-tiered management structure typical of medical institutions. In non-institutions the authorized user is likely to be part of management and a line supervisor for ancillary workers; therefore a formal committee structure would serve no useful purpose. A similar requirement was published as a proposed rule on April 9, 1979 (44 FR 21023), and as a final rule on September 13, 1982 (47 FR 40149).

Committee membership must include a physician identified on the institution's license as an authorized user or byproduct material for each type of use permitted by the license, the institution's Radiation Safety Officer, a representative of the institution's management, and a representative of the nursing service.

Institutions that only request a license for diagnostic sealed sources will be exempted from this requirement by license condition because the radiation safety program would not depend on the cooperation of individuals from several different departments. Packages would arrive infrequently, there would be no chance of contaminating an entire room or suite, no radioactive waste, no radioactive patients, and little chance of loss of material.

To assure the safety of workers and the public in light of site-specific exigencies, the Committee must review on the basis of safety: (1) The qualifications of each individual to be listed as an authorized user, and (2) each proposed method of use. In its reviews, the Committee should consider compliance with NRC regulations, special physical or chemical containment problems, the amount of byproduct material that will be used, and the relative hazard of the material, all in light of the licensee's facility and staff.

The Committee must review occupational exposures quarterly. A more frequent review would inappropriately emphasize normal and expected statistical variations in exposure data. A less frequent review would not provide for timely notice of unnecessary or unnecessarily high doses.

The quarterly review should be guided by two trigger levels for individual doses. The lower level would be a minimum level below which no action need be taken. Above the minimum level, the source of exposure should be determined and consideration given to methods of reducing the exposure rate. The higher level should trigger immediate intervention by the Radiation Safety Officer to reduce the exposure. The committee should review the appropriateness and completeness of the intervention, and should develop a permanent solution to maintain doses at a lower level.

The annual review of the safety program is needed to determine its adequacy in light of the current and projected use of all byproduct material. In the Commission's judgment, a review at least once each year is adequate to assure that exposures remain ALARA considering the few program adjustments typically made during any single year. More time between reviews might not permit the committee to make timely recommendations for reducing unnecessary worker, public, or patient exposure by, for example, changing space allocation, purchasing new equipment, or changing procedures.

Section 35.33 Requirement for authority and statement of responsibilities.

To ensure that material is used safely, the Radiation Safety Officer and Radiation Safety Committee need a clear statement of their duties from management so that questions about authority, responsibility, and jurisdiction do not keep these individuals from acting.

Section 35.34 Visiting authorized user

The uninterrupted provision of medical care occasionally requires a visiting authorized user to work for a host licensee when its permanent staff may be unable to do so. This was allowed in the past by a standard license condition. If the licensee had a copy of another licensee's NRC license that listed the visitor as an authorized user, the visitor could work under the license for sixty days each year without requesting a license amendment. The scope of this concept has been expanded to allow NRC licensees to employ Agreement State authorized users. Because the visiting authorized user's training and experience has been reviewed for health and safety consideration by a regulatory agency, this short-term authorization will not pose an undue risk to public health and safety. The purpose of written permission is to assure that the required records have been reviewed and found complete.

When exercising this privilege, host licensees should identify each individual method of use authorized by their license, each individual method of use authorized by the visitor's license, and each individual method of use that the visitor will be allowed to do at the host facility. Note that in some cases the Agreement States' groups, schedules, or subparts do not correspond to those of the NRC. The visitor can only do those procedures authorized by *both* licenses.

Section 35.35 Mobile nuclear medicine service administrative requirements.

Mobile nuclear medicine service has been limited to diagnostic medical use because the inherent hazard of therapeutic amounts of byproduct material makes it unsuitable for use in locations where the licensee might not have clear and direct control over personnel, facilities, or equipment. The Commission will continue, on a case-by-case basis, to authorize provision of low level radiopharmaceutical therapy by mobile nuclear medicine services. These licensees are required to have a letter of permission from the management of each client to assure that the client management is aware of and in agreement with the medical use of byproduct material within the facility.

Mobile service may not be provided to licensed clients because, in case of a spill or dose rates above regulatory limits, the responsibility for corrective action may be clouded.

Section 35.36 Radiation safety program changes.

This section allows the licensee to make changes in the radiation safety program that was described in the application if the changes are within the requirements of the regulation. The purpose of this authorization is to allow the licensee to respond to changes in staff levels, available equipment, or patient load that may require reallocation of floor space, or to make changes that may be necessary for patient care, administrative, radiation safety, or economy needs. Before implementing any change, the licensee must make a record of safety matters that were considered when planning the change. The record will be used during unannounced inspections to determine whether the licensee has made changes that are contrary to the regulations, license conditions or orders, and during termination surveys to provide an indication of every area where material was used.

The Commission notes that this change in the current licensing process under which *all* radiation safety program changes must be approved by license amendment, recognizes that, in the end, public health and safety is based on three features: (1) NRC regulates who may use byproduct material for medical use by listing authorized users on the license; (2) NRC regulates the degree of hazard, balanced with medical needs, by only allowing certain chemical and physical forms for medical use; and (3) NRC regulates where byproduct material may be used to allow for unannounced inspections of licensee radiation safety programs. This proposal would retain those regulatory features by requiring licensees to receive a license amendment before using material for new clinical methods of use not permitted by the license; before permitting new authorized users to use material; before receiving more material or different kinds of material than permitted by the license; and before using material at locations not listed on the license. These are major changes in a licensee's radiation safety program for which a license amendment would still be required (see § 35.17). Under this proposal all other changes (such as selecting replacement equipment, re-arranging the nuclear medicine clinic, switching from one service contractor to another, or switching to an alternative equipment quality assurance procedure) would be minor changes.

The Commission would appreciate comments on this major/minor dividing line or threshold. Is this dividing line clear and complete? Are there other features that should be considered as major changes, or are some of these major changes really not important to health and safety? Is there some other dividing line, either fixed or flexible, that would clarify which changes are really not important to health and safety and may therefore be made by the licensee? Alternatively, should the Commission continue to require licensees to submit all radiation safety program changes for agency approval?

Section 35.37 Records and reports of misadministrations.

The proposed Part 35 retains the misadministration definitions and reporting and recordkeeping requirements of the current Part 35. A discussion of these requirements appears at 45 FR 31701, published May 14, 1980.

Although the Commission has not revised its misadministration reporting and recordkeeping requirements, it would like to take this opportunity to ask for public comment on these requirements based on the experience gained since the requirements were first published in final form five years ago. For both diagnostic and therapeutic misadministrations, are the current requirements adequate to protect the public health and safety or should they be made more or less stringent? Should the regulations require prompt notification of the patient who received the misadministration? Do the regulations provide the public with a clear notice of the Commission's role when there is misadministration? Should the Commission take enforcement action against licensees who misadminister byproduct material or radiation to patients? If so, what type of enforcement action should be taken?

Section 35.38 Supervision.

The authorized user is allowed to use byproduct material in the practice of medicine. Frequently, specific tasks may be delegated (under §§ 35.2(b) and 35.38) to individuals with less training and experience. However, it is necessary that a qualified individual instruct them, oversee their work on a frequent basis, and be available to promptly respond in unusual or emergency situations. The regulation requires that supervised individuals comply with instructions, procedures, and the regulations.

The NRC has not specified which tasks may be delegated to whom because the practice of medicine is regulated differently in each State and because medical services must also be responsive to each community's particular needs. The NRC particularly requests comment on whether special training elements should be clearly identified for certain tasks that are delegated or whether the general guidance is sufficient.

Section 35.49 Suppliers.

In order to authorize only the use of materials reviewed by the government for safety and effectiveness considerations, authorized users may use only byproduct material that has been manufactured and distributed under procedures that were reviewed for safety by the NRC, the Food and Drug Administration (FDA), or an Agreement State.

The NRC will continue its current practice of allowing, on a case-by-case basis, re-transfer of radiopharmaceuticals between Part 35 licensees if an applicant specifically requests an exemption from this section and shows the exemption is in the public interest.

Subpart C—General Technical Requirements

Section 35.50 Possession, use, calibration, and check of dose calibrators.

A dose calibrator is needed to ensure that the dosage of material given is the dosage that was prescribed. It must be tested for accuracy, the ability to exactly measure a specified quantity and linearity, the ability to exactly measure a range of quantities. The requirements are generally consistent with the recommendations of the American National Standards Institute. (See ANSI N42.13–1978). Copies may be purchased by contacting Sales Department, American National Standards Institute, 1430 Broadway, New York, NY 10018. In the interest of economy and efficiency, the NRC uses voluntary national standards in its regulatory program if they provide adequate assurance of safety.) The activity levels of the accuracy check sources were chosen because a lower activity would invalidate the accuracy test due to expected statistical fluctuations, and a higher activity would present an unnecessary source of radiation exposure to workers. The radionuclides required reflect the fact that dose calibrators are not as accurate as might be expected for the photon energies commonly used for imaging (see "Joint NCDRH and State Quality Assurance Surveys in Nuclear Medicine," HHS Publication FDA 83–8209). The linearity test should only be done over the range between highest individual dosage measured and 10 microcuries to ensure that the dosage given is the dosage that was prescribed. It is not necessary to test for linearity for all amounts that might be measured, for example the first elution from a fresh generator or a multidose vial, because this would subject the worker to unnecessary radiation dose. Dosages below 10 microcuries cannot be accurately measured on a conventional dose calibrator because they are so tiny. Also, these dosages present only a trivial risk to the patient and therefore need not be so accurately measured. The geometry test assures that the shape of the syringe or vial containing the byproduct material does not affect the dosage measurement. The daily constancy check assures that the dose calibrator has worked consistently since it was last tested.

Licensees whose level or scope of use does not indicate need for a dose calibrator may request an exemption from this section. The request should be supported by a description of an alternative method that the licensee will use to measure radiopharmaceutical dosages.

Section 35.51 Calibration and check of survey instruments.

The 1000 mR/hr limit was chosen because that is the highest radiation exposure rate that is likely to be encountered in the medical environment. The calibration frequency and the other prescriptive and performance requirements in this section are generally consistent with ANSI N323–1978.

Section 35.53 Measurement of radiopharmaceutical dosages.

This section requires that the licensee assay the radioactivity of each radiopharmaceutical dosage before it is administered to a patient and keep a record of the assay results. This is required to ensure that the patient receives the intended dosage. The time at which the measurement must be made has been purposefully omitted to allow for flexibility in licensee's procedures.

A similar requirement was published as a proposed rule on September 1, 1981 (46 FR 43840). The comment period on the proposed rule expired November 30, 1981. The NRC is incorporating the dosage measurement proposal in this revision. The proposed Part 35 dosage measurement requirement differs from the 1981 proposal in its recordkeeping requirement. The Part 35 proposal requires the dosage measurement record to include the patient's name, and identification number if one has been assigned, and prescribed dosage. This information was not required by the 1981 proposal.

Section 35.58 Authorization for calibration and reference sources.

These sources are needed to check and test radiation instruments and to mark images. They represent a small radiation hazard in relation to the amount of radioactivity used in patient care. The activity level was chosen to allow licenses to have a range of sources with several energies and half-lives available.

Section 35.59 Requirements for possession of sealed sources and brachytherapy sources.

The user must follow the manufacturer's instructions because they have been reviewed for safety considerations by the Commission or an Agreement State.

The six-month test interval has been recommended by the National Council on Radiation Protection and Measurements (NCRP)[1] in Report No. 57, "Instrumentation and Monitoring Methods for Radiation Protection." More frequent testing is inconsistent with ALARA considerations because it would cause worker dose when making the test but provides only a slightly greater probability of funding a leaking source. The test procedures described are intended to maximize the probability of detecting contamination from a leaking source. Report No. 57.

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[1] The National Council on Radiation Protection and Measurements (NCRP) is a nonprofit corporation chartered by Congress in 1964 to draft proposed recommendations on protection against radiation and on radiation measurements, quantities, and units, particularly those concerned with radiation protection. Copies of reports may be purchased by contacting NCRP Publications, P.O Box 30175, Washington, DC 20014.

Section 3.3.5.3 recommends a minimum detectable limit of 0.005 microcuries for equipment used to measure leak test samples. This level is also consistent with the requirements of other parts of the current regulations (see, for example, §§ 31.5 and 34.25), and is only slightly higher than the minimum detectable activity exhibited by instrumentation available to licensees. The Commission has made a judgment that this level provides the most conservative detection level technically achievable at a reasonable cost. It is noted that this requirement would reduce the current permissible amount of detectable contamination from teletherapy sources ten-fold, from 0.05 microcuries to 0.005 microcuries for purpose of consistency.

The Commission has made a judgment that the exempted sources do not present a contamination hazard because of the small amount of radioactivity in the sources, the method in which they are constructed, or the small hazard of the byproduct material. To conduct a physical inventory more frequently than quarterly is inconsistent with ALARA exposure goals. To inventory less frequently may, in case of a misplaced source, allow an unacceptable radiation exposure to go on for too long without detection. The radiation survey assures that sources are safely stored.

Section 35.60 Syringe shields.

Syringes that contain byproduct material can be an external radiation source and should therefore be shielded at all times. In some cases the use of a shield when making an injection could interfere significantly with the injection. This would jeopardize patient benefit. In such cases the higher radiation exposure to the hands that is received by the technician who does not use a syringe shield is warranted. A shield need not be used when the risk of spoiling the injection is greater than the benefit of reduced worker exposure.

The NRC considered requiring the use of syringe shields when drawing individual dosages from multi-dose vials. That requirement is not included in this proposed revision because it appears that the increased handling required to remove the shield when measuring the dosage may actually increase radiation dose to the hands. However, the NRC is soliciting comments on whether syringe shields should be used when drawing individual dosages.

Section 35.61 Vial shields.

A vial radiation shield can significantly reduce the radiation exposure to the fingers and hands of an individual handling a vial of byproduct material.

Section 35.62 Syringe labels, and § 35.63 Vial shield labels.

Some misadministrations have been caused by accidentally transposing vials or syringes. The proper labelling of containers will help to avoid this type of mistake.

Section 35.70 Surveys for contamination and ambient radiation exposure rate.

Since radiopharmaceuticals are frequently handled, it is plausible that a syringe or some radioactive waste may be misled. This would result in unnecessary radiation exposure to workers and the public. The exposure rate survey will bring this to the attention of workers. The weekly exposure rate survey of waste storage areas will ensure that exposure rates in that area will be monitored so that special steps can be taken if greater than average use of radiopharmaceuticals results in higher than average exposure rates in the waste storage area.

The Commission knows that a removable contamination wipe test made several days after spillage of a short-lived radiopharmaceutical will probably not detect any contamination. The periodic contamination survey serves as a check of workers' physical control of radiopharmaceuticals. If contamination is found, it indicates that controls or safety measures may be inadequate or are not always being used.

Section 35.75 Release of patients containing radiopharmaceuticals or permanent implants.

A patient whose body contains byproduct material is a source of external radiation and can be a source of radioactive contamination. The patient should not be released from the clinic or hospital until the residual radioactivity in the patient is at an acceptable level. The Commission proposes to allow patient release limits based on residual activity in the patient or exposure rate at a specified distance from the patient at the licensee's option. The 30 millicuries burden limit is based on a recommendation of the NCRP and current licensing practice. The 5 mR/hr at one meter limit is based on the exposure rate from 30 millicuries of iodine-131, the most commonly used therapeutic radiopharmaceutical; some individuals believe that the exposure rate is more relevant and easier to measure. The Commission believes that either limit provides an adequate measure of safety for the general public, and that further reductions in public exposure are not reasonably achievable considering the cost and potential for detrimental effect from an unnecessarily long hospital confinement.

Section 35.80 Mobile nuclear medicine service technical requirements.

The Commission has limited radiopharmaceutical transportation by these licensees to unit dosage and multidose vials of prepared radiopharmaceuticals.

The Commission did not authorize transportation of generators because they are needed by persons who do not have daily access to prepared radiopharmaceuticals. That lack of access would be contrary to the geographic proximity required by § 35.38.

The service must remove all radioactive waste generated during the use of byproduct material at a client location of use because the Commission has no assurance that the client is equipped to safely receive and process radioactive waste. Because there is no assurance that the licensee can control access to areas of use while working in a facility that is under another person's administrative control, client facilities should be considered as unrestricted areas, and the licensee must therefore constantly exercise physical control of byproduct material.

Equipment checks are needed to assure the proper function of equipment after transport and before byproduct material is handled. A survey is needed to assure that all byproduct material has been removed from the client location of use. The mobile nuclear medicine service must carry a calibrated survey meter to monitor exposure and contamination in case of any accident that may result in a release of byproduct material.

Section 35.90 Storage of volatiles and gases.

Some radiopharmaceuticals present an inhalation or immersion source (e.g., volatile iodine-131 and xenon-133 respectively). The chance of exposure can be reduced by storing these materials in a fume hood or multiple barriers (such as a folded plastic bag within a folded plastic bag).

Section 35.92 Decay-in-storage.

For most hosptial radiopharmaceutical waste, decay to background levels is essentially complete over a period of days or months. The waste disposal requirements of § 20.301, directed primarily at longer half-lived material, are not necessary for short half-lived radiopharmaceutical waste. Therefore, short half-lived waste can be exempted from the requirements of § 20.301. A decay period of ten half-lives was chosen because it represents a thousand-fold reduction in radioactivity. This ensures that, in most cases, byproduct material will have decayed to levels below those in § 30.71, which are quantities that, under certain ordinary conditions, are exempt from a requirement for a specific license. The regulation would only allow decay-in-storage for radioactive material with a half-life of 65 days or less because storage for the required ten half-lives would be in excess of 650 days and more appropriately considered permanent storage. (Consistent with current practice, the Commission will consider, on a case-by-case basis, requests to decay longer-lived material or to decay for fewer half-lives.) Waste must be monitored to assure that long-lived waste was not accidentally mixed with short-lived waste and that no waste has been added to the container since it was sealed. When the waste is monitored, neither the waste nor the survey instrument may have any radiation shielding because it might hide the presence of long-lived byproduct material in the waste. The requirement to remove or obliterate radiation labels is in § 20.203(f)(4) and is included here for completeness. Generator columns must be individually monitored because they contained larger amounts of radioactivity and also may have small amounts of long-lived contaminants.

Subpart D—Uptake, Dilution, and Excretion

Section 35.100 Use of radiopharmaceuticals for uptake, dilution and excretion studies, and § 35.200 Use of radiopharmaceuticals, generators, and reagent kits for imaging and localization studies (§ 35.200 is also discussed later).

Drugs approved for human use by the FDA have a label or package insert that specifies the FDA-approved use, physical form, route of administration, and dosage range. NRC relies primarily on FDA's determination of a radioactive drug's safety and effectiveness when it is used according to the package insert. By restricting the physician to the FDA-approved physical form, route of administration, and dosage range, NRC assures the safety of the public while allowing the physician flexibility regarding the choice of the clinical procedure.

The Commission notes that the FDA is considering a change in its regulations for reviewing the safety of investigational new drugs and new uses of approved drugs (see 48 FR 26720, published June 9, 1983). The Commission may revise its regulations regarding investigational new drugs and new uses of approved drugs after reviewing FDA's final rulemaking.

The FDA also authorizes the Radioactive Drug Research Committee (RDRC) at an institution to review and approve the use of radioactive materials for medical use research purposes. The Commission believes that the guidelines used by the FDA when reviewing the credentials of the RDRC members, and the guidelines that the FDA requires the RDRC to use when evaluating research proposals, are adequate to assure the safety of workers and the public without unduly restricting medical research. Therefore, the Commission will continue to allow, on a case-by-case basis, licensees to administer radiopharmaceuticals authorized by an RDRC in accordance with FDA regulations. This authorization was not included in the regulation because only a few licensees request it.

The radiopharmaceuticals listed in § 35.100 were taken from those listed in the current §§ 35.31 and 35.100(a). Those listed in § 35.200 were taken from current §§ 35.100 (b) and (c). Mercury-203 was not included in the proposed revision because the Commission believes that there are other radiopharmaceuticals available that provide equivalent diagnostic information with much less radiation dose to the patient.

Manufacturers are currently distributing generally licensed radiopharmaceuticals under a license issued pursuant to § 32.70. If this revision is adopted by the Commission, these manufacturers would have to apply for a license amendment to distribute radiopharmaceuticals pursuant to § 32.72.

Section 35.120 Possession of survey instrument.

A low level survey instrument is needed to check areas of use for contamination. Since the total amount of radioactivity used for uptake, dilution, and excretion studies is relatively small, the Commission does not believe the licensee needs an ionization survey instrument to measure dose rates.

Subpart E—Imaging and Localization

Section 35.200 Use of radiopharmaceuticals, generators, and reagent kits for imaging and localization studies.

Xenon-133 as a gas or as saline solution has been added to this group. Manufacturers are currently distributing the product under a license issued pursuant to Part 30. If this revision is adopted by the Commission, these manufacturers would have to apply for a license amendment to distribute xenon pursuant to § 32.72.

Through continuing medical research, new uses may be found for existing approved radiopharmaceuticals. These new uses, which may require a different dosage, route of administration, or physical form, may not appear on the manufacturer's label or package insert instructions. It was such a situation that resulted in a petition filed by Dr. George V. Taplin (Docket No. PRM-35-1) requesting an exemption for Tc-99m pentetate as an aerosol for lung function studies. A proposed rule was published on April 13, 1982 (47 FR 15798). The comment period on this proposed rule expired June 14, 1982, and 35 comments were received. The NRC adopted the rule in final form without change on February 4, 1983 (48 FR 5217); the preamble of the final rule also described how to apply for future exemption requests. The NRC is incorporating this regulation into this revision of Part 35 without soliciting public comment because of the recentness of the rulemaking and because there are no substantive changes to the rule as adopted.

Section 35.204 Permissible molybdenum-99 concentration.

Technetium-99m is produced when molybdenum-99 undergoes radioactive decay. When the technetium is separated from the molybdenum, unwanted molybdenum may appear as a contaminant in the technetium solution. The permissible concentration of molybdenum-99 was chosen to be consistent with the permissible concentration listed in the United States Pharmacopeia (USP), the nationwide standard for all pharmaceuticals used in the practice of medicine. It is the judgment of the Commission that the USP standard provides an adequate level of safety and to require a different standard would be confusing and unproductive. Since diagnostic dosages of technetium-99m are generally 30 millicuries or less, the maximum permissible level of molybdenum-99 in such a dosage would result in a patient receiving an undesired 4.5 microcuries of molybdenum-99. The molybdenum would be taken up primarily by the liver. The dose to the liver would be about 0.2 rads as a result of the molybdenum concentration. The Commission has made a judgment that, by holding the permissible concentration to the required level, the resulting radiation dose is insignificant compared to the radiation dose which would be received by the patient due to the administration of the technetium.

The licensee that elutes the generator must measure and keep a record of the molybdenum concentration. Persons who receive prepared radiopharmaceuticals do not have to make this measurement because the person who prepared it would have made the measurement (see the conforming amendment to § 30.34).

Section 35.205 Control of aerosols and gases.

The Commission believes that a system that provides for the collection or controlled dispersal of aerosols and gases is needed to reduce exposure to workers and the public. If control is by dispersal in the atmosphere, licensees should note §§ 20.105 and 20.106, which limit the amount of radioactivity in the effluent stream.

Unlike solid and liquid byproduct materials authorized by this part, gases usually cannot be contained or recovered after a spill. To reduce exposure to workers and the public after a spill, exhaust and dispersal in the atmosphere is commonly used. However, because conventional room ventilation rates are seldom sufficient to clear spilled gas in a timely fashion, the licensee must follow special, room-specific safety measures in case of a gas spill. When making the required exhaust calculation, the licensee must assume that the largest single gas container handled in the area is completely spilled, and may use either ambient or emergency air exhaust rates.

Section 35.220 Possession of survey instruments.

The licensee needs a low level survey instrument to check for contamination and an ionization type instrument to measure dose rates in areas where large amounts of radioactive material are stored.

Subpart F—Radiopharmaceuticals for Therapy

Section 35.300 Use of radiopharmaceuticals for therapy.

The radiopharmaceuticals listed in § 35.300 were taken from those listed in the current §§ 35.100 (d) and (e). The drugs have been approved for medical use by the FDA.

Section 35.310 Safety instruction, and § 35.410 Safety instruction.

In the hospital setting, the use of byproduct material presents special training problems which are not addressed in Part 19 because they are unique to the medical environment. For example, visitor control in a hospital cannot be accomplished by physical barriers which might impede the delivery of emergency medical care to patients. After administration, the byproduct material is contained in an ambulatory human.

Therefore, the Commission has made a judgment that worker instruction in addition to that required by Part 19 is necessary. (This parallels special instruction required, for example, for radiographers and radiographers' assistants pursuant to § 34.31 of the Commission's regulations.)

Section 35.315 Safety precautions.

Because of the special contamination hazards of radiopharmaceutical therapy patients, a private room with private sanitary facilities is needed to protect members of the public, who might be visiting nearby patients, from unnecessary exposure to radiation. The RSO must be notified in case of the patient's death or medical emergency in order to determine whether special contamination control procedures must be implemented.

Section 35.320 Possession of survey instruments.

The licensee needs a low level survey instrument to check for contamination and an ionization type instrument to measure dose rates in areas where large amounts of radioactive material are stored.

Subpart G—Sources for Brachytherapy

Section 35.400 Use of sources for brachytherapy.

This section identifies brachytherapy sources that may be used for medical use. The list was taken from the current § 35.100(e), which is a list of sources commonly used for patient care.

Section 35.404 Release of patients treated with temporary implants.

A responsibility of the Commission is to restrict the movement of byproduct material when the public exposure would be increased. Brachytherapy sources for temporary implants have high levels of radiation, and remain radioactive for a long period of time. Loss of control of these sources and their release to unrestricted areas may result in potentially lethal radiation exposure to members of the public. The Commission has made a judgment that temporary confinement of the implant patient is necessary to ensure public safety. Section 35.404 requires that the licensee prevent the patient from leaving the hospital or clinic until all temporary implant sources have been removed. The records required by this section may be amalgamated with the records required by § 35.406; there is no need for duplication.

Section 35.406 Brachytherapy sources inventory.

Because of the particular hazard of brachytherapy sources due to their high activity and small size, the Commission believes that an inventory procedure that requires a physical count and a radiation survey log entry each time sources are handled with help to ensure that if a source is misplaced its absence will quickly become apparent to the licensee, which can then promptly begin a search for the source.

Section 35.415 Safety precautions.

Because of the high exposure rates around implant patients, a private room is needed to protect members of the public, who might be visiting nearby patients, from unnecessary exposure to radiation. The RSO must be notified in case of the patient's death or medical emergency to ensure that control of implant sources is retained.

Section 35.420 Possession of survey instrument.

The licensee needs a high level survey instrument to measure exposure rates in storage areas around a patient's room, and to check to be sure all sources have been removed from the patient before release from confinement.

Subpart H—Sealed Sources for Diagnosis

Section 35.500 Use of sealed sources for diagnosis

This is a new type of use group established to incorporate the recent development of medical devices that use a sealed source of byproduct material to create a beam of ionizing radiation. These devices are now available to persons licensed to use materials listed in § 35.100(f). Because the devices represent a lower level of hazard than the other sources in that group, the Commission has determined that these devices should comprise a new group.

Section 35.520 Availability of survey instrument.

The licensee needs a survey instrument to measure the exposure rates around a packaged sealed source that was just received or that is to be returned to the manufacturer, and to survey for contamination in case of an accident that might have compromised the intergrity of the sealed source. However, because a source exchange is an infrequent and scheduled event, and because a hazardous accident would be a very rare occurrence, the Commission believes that it is sufficient, for safety purposes, to require the licensee to make arrangements to borrow or rent an instrument or contract with a measurement service when measurements are necessary.

Subpart I—Teletherapy

Section 35.600 Use of a sealed source in a teletherapy unit.

This is a new type of use group established to deal with a well-established type of use. Safety measures that now apply to all licensees within this group have been used over the years and are reflected in these proposed regulations.

Section 35.605 Maintenance and repair restrictions, and § 35.645 Five-year inspection (§ 35.645 is also discussed later).

These sections provide notice that only specially licensed persons may maintain, adjust, or repair teletherapy units because this type of work requires special training and equipment in order to be done safely. This work is licensed under Part 30 of the Commission's regulations.

Section 35.606 Amendments.

Amendments are required for items identified in paragraphs (a) through (e) because any change described in these paragraphs could easily result in an increase in radiation levels in excess of the levels authorized in § 20.105. The service of a qualified teletherapy calibration expert is an essential element in ensuring the safe use of a teletherapy unit. The Commission has made a judgment that only an individual with special training and experience can determine the operating characteristics of the licensee's teletherapy unit and should therefore be identified on the license.

Section 35.610 Safety instructions.

Emergency instructions must be posted to remind individuals of the proper steps to be taken in case of an emergency and to identify individuals to be notified in an emergency. The Commission believes this is also an appropriate place to remind workers that it is important to ensure that only the patient is in the room before turning the unit on. The reminder is necessary because it is possible that when two workers are stationed on one teletherapy unit one worker may inadvertently turn the unit on when the other worker is still in the treatment room, or a worker may turn the unit on to check its operation after a patient or co-worker has entered the treatment room without telling the worker at the control console.

The special instruction for teletherapy workers is needed because this is the one type of medical use of byproduct material in which a worker or member of the public could receive a high, whole body dose in a matter of minutes if the source were not used safely.

Section 35.615 Doors, interlocks, and warning systems.

NCRP Report No. 57, "Instrumentation and Monitoring Methods for Radiation Protection," on page 42, states that a survey of a new teletherapy facility must determine that . . ." All entrances into the irradiation room or other high radiation areas are provided with barriers equipped with interlocks that are not dependent on the operation of a single circuit, and that will interrupt radiation production when the barrier is opened." There have been incidents in irradiation facilities in which personnel were unnecessarily exposed to radiation because door interlocks or alarms were intentionally bypassed for convenience. See, for example, cases 19, 21, and 28 in NUREG/BR-0001, "Case Histories of Radiography Events," vol. 1, 1980. If the interlocks and warning systems had not been bypassed, personnel would not have been irradiated. The Commission, however, has made a judgment that the dual warning system of a door interlock and a radiation monitor in the teletherapy room obviates the need for the dual circuit door interlock recommended in the report.

The beam condition indicator light will indicate to workers about to enter the room whether the unit is turned on or off.

Section 35.620 Possession of survey instrument.

The licensee needs a survey instrument on hand as a backup room monitoring device in case the radiation monitoring device fails.

Section 35.621 Radiation monitoring device.

The radiation monitoring device is needed to indicate radiation levels in the teletherapy room if the interlocks or the warning systems fail. Individuals may be unnecessarily exposed following the failure of the source retraction mechanism coupled with a failure of the primary beam condition indicator system. Therefore, § 35.621 requires licensees to install a permanent radiation monitor in each teletherapy room, to check its operation before using the teletherapy unit, and to use portable survey instrument or personal audible alarm dosimeter if the monitor is inoperable. Similar requirements were published as a proposed rule on April 28, 1982 (47 FR 18131), and were adopted in a final rule published January 18, 1983 (48 FR 2116).

Section 35.622 Viewing system.

If a patient moved during a therapy administration, this could result in a radiation dose to healthy tissue and no dose to the treatment area. Therefore, a viewing system is needed to monitor the orientation of the patient and the teletherapy unit to assure the prescribed application of radiation.

Section 35.630 Dosimetry equipment.

Dosimetry equipment is needed to measure radiation output. In order to help assure accuracy the equipment must be calibrated. The equipment requirements are the same as the current §§ 35.22 and 35.23. This section also contains the proposed resolution of the petition filed by the American Association of Physicists in Medicine, Petition Docket No. PRM 35-2 (see 47 FR 4311, January 29, 1982). Currently, regulations require that primary dosimetry equipment be calibrated every two years. The petitioner requested that this two year requirement be relaxed to four years if, two years after calibration, the primary dosimetry system is intercompared with a system that was calibrated within the past two years, and the results of the intercomparison indicate that the calibration factor used to convert an instrument reading to a dose measurement had not changed by more than two percent. (Intercomparison meetings are occasionally scheduled by several qualified teletherapy calibration experts within a geographic area. Each expert takes a dosimetry system of *similar* metrological quality to the meeting. Each dosimetry system in turn is exposed to the same radiation dose from a teletherapy unit. The response of each dosimetry system can then be compared to the response of the other systems. If each system measures the same radiation dose in rads, this provides assurance that each system is working properly. Note that when instruments of *different* metrological quality are exposed to the same radiation dose, it is referred to as a comparison rather than an intercomparison.) This suggestion has been incorporated into these proposed regulations. The petitioner also asked that the licensee be required to make quarterly constancy checks to assure the consistency of operation of the dosimetry system. The Commission did not incorporate this suggestion because it is not aware of any scientific study that shows that such checks, when made with currently available equipment, are capable of detecting small but significant changes in calibration. Therefore, the Commission has no basis to assume that periodic constancy checks would necessarily provide increased assurance of proper operation.

Section 35.632 Full calibration measurements.

Full calibrations are needed to ensure that the given dose is the same as the prescribed dose. The required frequency of full calibrations remains unchanged from that of the current Part 35. The test for timer accuracy has been clarified to include on-off error. The accuracy of localization devices that are used to position the teletherapy patient has been added to minimize the risk of unintentional irradiating healthy tissue. The function of mechanical and electrical interlocks that are used to limit the directions in which the beam can be aimed, and thereby reduce the exposure rate in uncontrolled areas, has also been added. The licensee need no longer perform all measurements with a calibrated dosimetry system. Instead, the calibrated dosimetry system need only be used for one representative measurement, and then a relative exposure rate measurement system can be used to complete the calibration. This would allow for use of computer-controlled dosimetry systems that are capable of making precise relative measurements but are not suitable for making absolute output measurements.

The Commission proposes to allow licensees to use either the currently required calibration procedure or a new procedure that was recently published. The new procedure is generally considered more scientifically rigorous, but the Commission believes that either procedure provides an adequate measure of teletherapy dose rate.

The exposure rate from a radioactive source goes down as time progresses due to source radioactive decay. To ensure accurate dose delivery, the regulation requires that licensees mathematically take this into account in calculating patient doses. The regulation requires that the licensee use time periods of not longer than one month when making decay calculations. This will ensure that the actual dose does not differ from the calculated dose by more than one percent due to this decay error.

Section 35.633 Periodic spot-checks, and § 35.642 Safety checks for teletherapy facilities.

A monthly spot-check is required by § 35.22 of the current regulations to ensure that the teletherapy unit is giving the expected radiation dose. The following changes from current requirements have been made. Timer accuracy has been clarified to include on-off error. The accuracy of localization devices has been added. Error in either may result in incorrect administration of radiation. The qualified teletherapy calibration expert must review the results of the spot-check measurements within fifteen days, and must notify the licensee in writing of the results of the monthly check, to assure the licensee and the Commission that the check results were reviewed by a qualified individual. The Commission has made a judgment that a response period of less than fifteen days would be unreasonably expensive.

A requirement to check certain safety systems in the teletherapy facility has been added. These checks are needed to assure that safety systems required by other sections of the regulations are working properly. They need not be performed by the qualified teletherapy calibration expert. Devices that are not working must be promptly repaired in order to assure safety in the teletherapy facility. In case of failure of the viewing system, the regulation would allow the physician to decide whether treatments should be interrupted. This would *not* relieve the licensee from the requirement to promptly repair the viewing system. The regulation would require that the teletherapy unit not be used in case of door interlock failure because that is the mechanism that protects workers and the public from unintentional irradiation. However, the Commission invites comment as to whether additional administrative procedures or personal supervision would provide an acceptable balance of worker safety and medical use needs.

Section 35.641 Radiation surveys for teletherapy facilities.

The Commission has used these maximum and average permissible source leakage radiation levels for several years as license conditions. They are consistent with guidance from the NCRP in its Report No. 33, "Medical X-ray and Gamma-ray Protection for Energies up to 10 MeV-Equipment Design and Use." Section 4.2.2. The Commission has made a judgment that they are sufficiently restrictive to keep exposures as low as reasonably achievable. The required location of the collimators during the head leakage survey is a new specification. It is based on the fact that, for individuals who receive most of their radiation dose from working around a source in the "off" position, the collimators will normally be at the setting used for the last treatment.

Section 35.643 Modification of teletherapy unit or room before beginning a treatment program.

The section is needed to require that licensees take prompt action to reduce exposure rates in uncontrolled areas that may be caused by errors in design or construction of the teletherapy facility.

Section 35.644 Reports of teletherapy surveys, checks, tests, and measurements.

Given the potential for high exposure to workers and the public from improperly installed teletherapy units, the radiation survey information required by § 35.644 is needed to assure that teletherapy units have been properly installed and are sufficiently shielded to ensure compliance with the exposure limits of Part 20.

Section 35.645 Five-year inspection.

Many licensees replace teletherapy sources at five year intervals. Requiring a mechanical check at five year intervals helps to assure that the source exposure mechanism is in good working order and will not stick in the exposed position. The mechanic who exchanges sources and inspects units can remove the source, inspect the drawer mechanism, and then install the new source. More frequent checks would require greater time near a very radioactive source. Less frequent checks would not be sufficient to assure the continuous proper operation of the exposure mechanism. The identification information in the record is needed to establish which unit was inspected, when, and by whom. The remaining information is needed so the Commission may determine that the inspection was of sufficient depth to assure the health and safety of workers and the public.

Subpart J—Training and Experience Requirements

A combination of theoretical and practical training and experience is necessary to assure the safe use of byproduct material. The criteria in this subpart were developed by the staff with the advice of the Advisory Committee on the Medical Use of Isotopes (ACMUI). The requirements for the Radiation Safety Officer have not been published before. The requirements for authorized users are similar to those published as an amendment to Appendix A of Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Programs," in the **Federal Register** on December 2, 1982 (47 FR 54376). The requirements for the qualified teletherapy calibration expert are similar to those required of a qualified expert pursuant to the current § 35.24.

Consistent with current practice, if individuals do not meet the training and experience standards, the NRC will review their credentials with regard to the materials requested and these standards and make authorizations on a case-by-case basis.

The Commission has received and is reviewing suggested altenative training standards for some methods of use. The review is being handled as a separate project. If any changes in training standards come out of that project, they will be published for public comment and incorporated into this subpart or elsewhere, as appropriate.

Sections 35.900(a), 35.910(a), 35.920(a), 35.930(a), 35.940(a), 35.941(a), 35.950(a), 35.960(a), and 35.961(a), concerning certification.

The Commission has made a judgment that in some cases, certification by an appropriate professional board provides proof of adequate training and experience because the criteria which must be met to attain certification are more stringent than the training and experience required by the Commission.

Section 35.900(c) Authorized user as a Radiation Safety Officer.

The training and experience required by the Commission includes safety considerations for the byproduct material that the authorized user may use. Therefore, authorized users are qualified to oversee the safe use of byproduct material that they are authorized to use pursuant to the conditions of the license.

Sections 35.900(b), 35.910(b), 35.920(b), 35.930(b), 35.940(b), 35.941(b), 35.950(b), 35.960(b), and 35.961(b) Training and experience.

The criteria identified in these sections were developed by the staff with the assistance of the ACMUI over the past several years. The Commission has made a judgment that, for each type of use, the training and experience described is necessary to ensure the safe use of byproduct material. The duration of training and experience is usually specified in classroom (not credit) hours. Training may be received as part of a formal program at an accredited university, at a proprietary school, from an equipment or radiopharmaceutical manufacturer, or elsewhere. NRC will carefully review this information before listing an individual on a license. Supervised work experience must be received at an institution under an authorized user preceptor because usually only such an individual is qualified to teach the clinical use of byproduct material, and, if the experience were not received at an institution, the student would be less likely to receive experience with all the methods of use commonly used or all the management problems associated with the safe handling of byproduct material.

Sections 35.910(c) and 35.920(c) Integrated programs.

The Accreditation Council for Graduate Medical Education (ACGME) reviews and approves training programs for physicians. Approval of these training programs is based, in part, on adequate radiation safety content. The Commission has made a judgment that individuals who have successfully completed an approved training program have received sufficient training and experience to use byproduct material safely.

Sections 35.901 and 35.970 Current Radiation Safety Officers and Authorized users.

The staff has reviewed and found acceptable the training and experience of each individual who is currently listed as a Radiation Safety Officer or an authorized user. Further review of the credentials of these individuals is unnecessary.

Section 35.971 Physician training exception.

In addition to the ACGME, the American Board of Radiology, the American Board of Osteopathic Radiology, and the American Board of Nuclear Medicine review and approve nuclear medicine training programs for physicians. These three boards independently arrived at the conclusion that, while currently acceptable, a three month training program may not allow sufficient time in the future to provide the training and experience needed to develop a satisfactory level of expertise in nuclear medicine, including radiation safety. All three boards and the ACGME have therefore extended their training programs to six months duration for those who begin their training after June 30, 1984. The Commission has made a judgment that, in the meantime, individuals who have successfully completed an approved three month training program have received sufficient training and experience to use byproduct material safely.

Section 35.972 Recentness of Training.

Radiation safety regulations and practices may be expected to change with time. The Commission has made a judgment that training received within the five years preceding submittal of an application is sufficiently up-to-date to assure the safe use of byproduct material. If an individual received training more than five years before the application and has not had continuing involvement in the field, training must be repeated.

Subpart K—Enforcement

Section 35.990 Violations.

This section gives notice that the Commission will initiate legal proceedings if necessary to enforce requirements.

Section 35.999 Resolution of conflicting requirements during transition period.

As discussed before, to allow for an orderly transition from licenses granted under the present regulations to licenses granted under the new regulations, if there is a conflict between the final rule and a licensee's radiation safety program as described in the statements, representations, and procedures submitted in support of the license request, and if the license was issued before the effective date of the final rule and has not been renewed, the requirements and authorizations of the licensee's radiation safety program will take precedence over the final rule. However, if the licensee exercises its right to make a radiation safety program change as authorized under § 35.36, the changed procedure must be in accord with the revised regulation.

Conforming Amendment

Section 31.11 General license for use of byproduct material for certain in vitro clinical or laboratory testing.

Many medical use licensees now use byproduct material for in vitro work under the provisions of current §§ 31.11 and 35.14(c). The proposed conforming amendment grandfathers them. In the future, new and renewal applicants will have to specifically request permission to use § 31.11 materials as a separate line item on their applications. The use of materials listed in § 31.11 within the inventory limits of that section will only be subject to the requirements of that section; consistent with current regulations, the use of materials listed in § 31.11 will *not* be subject to the requirements of Parts 19, 20, 21, and 35 except for the Mock Iodine-125 disposal, loss or theft, and notification clause of § 31.11(f).

Derivation Table

The following derivation table identifies the origin of each section of the proposed regulations. Sources of the proposed regulations include 10 CFR Parts 19, 30, and 35, Federal Register Notices (FR), frequently used license conditions, licensing staff policy, current regulatory guides (RG), Office of Inspection and Enforcement bulletins, the United States Pharmacopeia, and new text prepared by staff.

New Section Number	Origin
Subpart A—General Information	
35.1 Purpose and scope	35.1 revised.
35.2 License required	35.2 revised
35.8 Reporting recordkeeping, and application requirements: OMB Approval.	New text
35.15 Definitions:	
Agreement State	20.3.
ALARA	Acronym.
Authorized users	Term used on licenses.
Dentist	New term
Medical institution	Do.
Management	Do
Medial use	35.3(a) revised
Misadministration	35.41.
Mobile nuclear medicine service.	New term
Output	Do.
Physician	35.3(b) revised
Podiatrist	New term.
Qualified teletherapy calibration expert.	Do.
Radiation Safety Officer	Term used on licenses
Sealed source	30.4(r) verbatim.
Visiting authorized user	New term; similar to "visiting authorized user" license condition.
35.16 Application for license, amendment, or renewal.	35.4 revised.
35.17 License amendments	New text; compare 30.36.
35.18 Notifications	New text.
35.26 License issuance	New text; compare 30.36.
35.29 Specific exemptions	New text; compare 30.11.
Subpart B—General Administrative Requirements	
35.30 ALARA program	New text; see RG 10.8 Appendix O revised.
35.31 Radiation Safety Officer	RG 10.8.
35.32 Radiation Safety Committee.	35.11(b) revised.
35.33 Requirements for authority and statement of responsibilities.	New text.
35.34 Visiting authorized user	License condition.
35.35 Mobile nuclear medicine service administrative requirements.	Licensing policy.
35.36 Radiation safety program changes.	New text
35.37 Records and reports of misadministrations.	35.42.
35.38 Supervision	Expanded from RG 10.8 p. 3.
35.49 Suppliers	35.14 revised.
Subpart C—General Technical Requirements	
35.50 Possession, use, calibration, and check of dose calibrators.	RG 10.8 Appendix D2 revised, and new text
35.51 Calibration and check of survey instruments.	RG 10.8 Appendix D1 revised, and new text
35.53 Measurement of radio pharmaceutical dosages.	Proposed rulemaking 35.15 (46 FR 43840; September 1, 1981)
35.58 Authorization for calibration and reference sources.	35.14(d) revised.
35.59 Requirements for possession of sealed sources.	35.14(e)(1)(i), 35.14(f) revised.
35.60 Syringe shields	Inspection and Enforcement letter April 16, 1979
35.61 Vial shields	Inspection and Enforcement letter April 16, 1979.
35.62 Syringe labels	New text.
35.63 Vial shield labels	Do.
35.70 Surveys for contamination and ambient radiation exposure rate.	RG 10.8 Appendix I revised
35.75 Release of patients containing radiopharmaceutcais or permanent implants.	New text
35.80 Mobile nuclear medicine service technical requirements.	Licensing policy
35.90 Storage of volatiles and gases.	RG 10.8 Appendix M revised.
35.92 Decay-in-storage	License condition
Subpart D—Uptake, Dilution, and Excretion	
35.100 Use of radiopharmaceuticals, for uptake, dilution, and excretion studies.	35.31 and 35.100 (I) revised.
35.120 Possession of survey instrument.	RG 10.8 page 5
Subpart E—Imaging and Localization	
35.200 Use of radiopharmaceuticals, generators, and reagent kits, for imaging and localization studies.	35.100 (II) and (III) revised
35.204 Permissible molybdenum-99 concentration.	US Pharmacopeia.
35.205 Control of aerosols and gases.	RG 10.8 Appendix M revised
35.220 Possession of survey instruments.	RG 10.8 page 5.
Subpart F—Radiopharmaceuticals for Therapy	
35.300 Use of radiopharmaceuticals for therapy.	35.100 (IV) and (V) revised.
35.310 Safety instruction	19.12 revised.
35.315 Safety precautions	RG 10.8 Appendix K
35.320 Possession of survey instruments.	RG 10.8 page 5.
Subpart G—Sources for Brachytherapy	
35.400 Use of sources for brachytherapy.	35.100 (VI) revised.
35.404 Release of patients treated with temporary implants.	35.14(b)(5)(vii) revised.
35.406 Brachytherapy sources inventory.	RG 8.18 page 8.
35.410 Safety instruction	19.12 revised.
35.415 Safety precautions	RG 10.8 Appendix L.
35.420 Possession of survey instruments.	New text.
Subpart H—Sealed Sources for Diagnosis	
35.500 Use of sealed sources for diagnosis.	New text.
35.520 Availability of survey instrument.	New text.
Subpart I—Teletherapy	
35.600 Use of a sealed source in a teletherapy unit.	New text.
35.605 Maintenance and repair restrictions.	License condition
35.606 Amendments	New text.
35.610 Safety instruction	License condition and new text.
35.615 Doors, interlocks, and warning systems.	License condition.
35.620 Possession of survey instrument.	New text.
35.621 Radiation monitoring device.	35.25 (48 FR 2115; Jan 18, 1983)
35.622 Viewing system	License condition
35.630 Dosimetry equipment	35.22, 35.23 revised
35.632 Full calibration measurements.	35.21 revised
35.633 Periodic spot-checks	35.22 revised and license condition.
35.641 Radiation surveys for teletherapy facilities.	License condition.
35.642 Safety checks for teletherapy facilities.	License condition
35.643 Modification of teletherapy unit or room before beginning a treatment program.	New text.
35.644 Reports of teletherapy surveys, checks, tests and measurements.	License condition
35.645 Five-year inspection	License condition
Subpart J—Training and Experience Requirements	
35.900 Radiation Safety Officer	New text
35.901 Training for experienced Radiation Safety Officer.	Do.
35.910 Training for uptake, dilution, and excretion studies.	Do.
35.920 Training for imaging and localization studies.	Revision of Federal Register Notice (47 FR 53476; Dec. 2, 1982)
35.930 Training for therapeutic use of radiopharmaceuticals.	Revision of Federal Register Notice (47 FR 53476; Dec. 2, 1982)
35.940 Training for therapeutic use of brachytherapy sources.	Revision of Federal Register Notice (47 FR 53476, Dec. 2, 1982)
35.941 Training for ophthalmic use of strontium-90.	Revision of Federal Register Notice (47 FR 53476; Dec. 2, 1982)
35.950 Training for use of sealed sources for diagnosis.	New text.
35.960 Training for teletherapy	Revision of Federal Register Notice (47 FR 53476; Dec. 2, 1982)
35.961 Training for qualified teletherapy calibration expert.	35.24 revised.
35.970 Training for experienced authorized users.	New text.
35.971 Physician training in a three month program.	Do.
35.972 Recentness of training	Revision of Federal Register Notice (47 FR 53476; Dec. 2, 1982)
Subpart K—Enforcement	
35.990 Violations	New text
35.999 Resolution of conflicting requirements during transition period.	Do.

Administrative Statements

Finding of No Significant Environmental Impact: Availability

The Commission is proposing to completely revise the regulations governing the medical use of byproduct material. The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that promulgation of this regulation is not a major Federal action significantly affecting the quality of the human environment and therefore an environmental impact statement is not required. The radiation levels and release of byproduct material authorized by this proposed revision are consistent with the Commission's other regulations and internationally accepted standards. Most radiation experts agree that levels and releases that are within these regulations and standards will not have a significant effect on the quality of the human environment. The assessment analyzes the possible impact of release of radioactive patients, the transportation of byproduct material for medical use, storage, and control of aerosols and gases, waste disposal by decay-in-storage, and dose rates outside teletherapy rooms. The environmental assessment and finding of no significant impact on which this determination is based are available for public inspection at the NRC Public Document Room, 1717 H Street NW, Washington, DC. Single copies of the evironmental assessment and finding of no significant impact are available from Mr. McElroy (See "For further information contact:" heading).

Paperwork Reduction Act Statement

This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). This rule has been submitted to the Office of Management and Budget for review and approval of the paperwork requirements.

Regulatory Analysis

The Commission has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. The draft analysis is available for inspection in the NRC Public Document Room, 1717 H Street NW, Washington, DC Single Copies of the analysis may be obtained from Mr. McElroy (see "For further information contact:" heading).

The Commission requests public comment on the draft regulatory analysis. Comments on the draft analysis may be submitted as indicated in the ADDRESSES heading.

Regulatory Flexibility Certification

Based on the information available at this stage of the rulemaking proceeding, in accordance with section 605(b) of the Regulatory Flexibility Act of 1980, the Commission certifies that this proposed rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. The NRC has issued approximately 2500 medical licenses under 10 CFR Part 35. Of these, approximately 2200 are held by institutions, and approximately 300 by individual physicians. Most of the institutional licensees are community hospitals. The Small Business Administration size standards, 13 CFR Part 121, (49 FR 5037; February 9, 1984) classify a hospital or physician's office as a small entity if its average gross annual receipts do not exceed $3.5 million. Under these size standards, some NRC medical licensees could be considered "small entities" for purposes of the Regulatory Flexibility Act.

The number of medical licensees that would fall into the small entity category does not constitute a substantial number for purposes of the Regulatory Flexibility Act.

The primary objective of the proposed rule is to simplify the medical licensing process by consolidating requirements without lessening the protection necessary for public health and safety. This will be accomplished through incorporation of frequently used license conditions into the regulations and the elimination or modification of requirements that are not essential to the protection of public health and safety. These steps will make it easier for a licensee to determine what is required to obtain a license and what is required of licensees. Therefore, there should not be a significant economic impact on these small entities.

The Commission has prepared a preliminary regulatory analysis for this proposed regulation which contains information concerning the anticipated economic effect of this regulation on licensees and presents the basis for the Commission's belief that the proposed regulation would not result in significant additional costs to any licensees. It is available for public inspection in the NRC Public Document Room at 1717 H Street NW., Washington, DC. Single copies are available from Mr. McElroy (see "For further information contact:" heading).

Because of the widely differing conditions under which licensees covered by this proposed regulation operate, the Commission specifically seeks public comment from small entities. Any small entity subject to this regulation which determines that, because of its size, it is likely to bear a disproportionate adverse economic impact should notify the Commission of this in a comment that indicates:

(1) The licensee's size in terms of annual income or revenue, number of employees and, if the licensee is a treatment center, the number of beds and patients treated annually;

(2) How the proposed regulation would result in a significant economic burden on the licensee as compared to that on a larger licensee;

(3) How the proposed regulations could be modified to take into account the licensee's differing needs or capabilities;

(4) The benefits that would be gained or the detriments that would be avoided to the licensee, if the proposed regulations were modified as suggested by the Commenter; and

(5) How the regulation, as modified, would still adequately protect public health and safety.

List of Subjects

10 CFR Part 30

Byproduct material, Government contracts, Intergovernmental relations, Isoptes, Nuclear materials, Penalty, Radiation Protection, Reporting and recordkeeping requirements.

10 CFR Part 31

Byproduct material, Labeling, Nuclear materials, Packaging and containers, Penalty, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment.

10 CFR Part 32

Byproduct materials, Labeling, Nuclear materials, Penalty, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 35

Byproduct material, Drugs, Health devices, Health professions, Incorporation by reference, Medical devices, Nuclear materials, Occupational safety and health, Penalty, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 40

Government contracts, Hazardous materials—transportation, Nuclear materials, Penalty, Reporting and recordkeeping requirements, Source material, Uranium.

Under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553 the NRC is proposing to adopt the following revision of 10 CFR Part 35 and the following amendments to 10 CFR Parts 30, 31, 32, and 40.

1. 10 CFR Part 35 is revised to read as follows:

PART 35—MEDICAL USE OF BYPRODUCT MATERIAL

Sec.

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35.999 Resolution of conflicting requirements during transition period.

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 35.2, 35.17, 35.30 (a) and (b), 35.31 (a) and (b), 35.32, 35.33, 35.34(a), 35.36(a), 35.38, 35.49, 35.50 (a)–(d), 35.51 (a)–(d), 35.53 (a) and (b), 35.59 (a)–(c), (e)(1), (g) and (h), 35.60, 35.61, 35.62, 35.63, 35.70 (a)–(f), 35.75, 35.80 (a)–(e), 35.90, 35.92(a), 35.100(b), 35.120, 35.200 (b) and (c), 35.204 (a) and (b), 35.205, 35.220, 35.310(a), 35.315, 35.320, 35.400, 35.404(a), 35.406 (a) and (c), 35.410(a), 35.415, 35.420, 35.500, 35.520, 35.605, 35.606, 35.610 (a) and (b), 35.615, 35.620, 35.621 (a)–(d), 35.621 (f) and (g), 35.622, 35.630 (a) and (b), 35.632 (a)–(f), 35.633 (a)–(i), 35.641 (a) and (b), 35.642 (a) and (b), 35.643 (a) and (b), 35.645 (a) and (b), 35.900, 35.910, 35.920, 35.930, 35.940, 35.941, 35.950, 35.960, 35.961, 35.970, and 35.971 are issued under sec. 161b, 68 Stat. 948 as amended (42 U.S.C 2201(b)); and §§ 35.18, 35.30(c), 35.31(b), 35.32(b), 35.33(b), 35.34 (a) and (c), 35.35(b), 35.36(b), 35.37 (a)–(d), 35.50(e), 35.51(e), 35.53(c), 35.59 (d) and (e)(2), 35.59 (g) and (i), 35.70(g), 35.80(f), 35.92(b), 35.204(c), 35.310(b), 35.315(b), 35.404(b), 35.406 (b) and (d), 35.410(b), 35.415(b), 35.610(c), 35.621(e), 35.630(c), 35.632(g), 35.633(j), 35.641(c), 35.642(c), 35.643(c), 35.644 and 35.645(c) are issued under sec. 161o, 68 Stat. 950 as amended (42 U.S.C. 2201(o)).

Subpart A—General Information

§ 35.1 Purpose and scope.

This part prescribes requirements and provisions for the medical use of byproduct material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the protection of the public health and safety. The requirements and provisions of this part are in addition to, and not in substitution for, others in this chapter. The requirements and provisions of Parts 19, 20, 21, 30, 71, and 170 of this chapter apply to applicants and licensees subject to this part unless specifically exempted.

§ 35.2 License required.

(a) No person shall manufacture, produce, acquire, receive, possess, use, or transfer byproduct material for medical use except in accordance with a specific license issued by the Commission or an Agreement State and as allowed in paragraph (b) of this section.

(b) An individual may receive, possess, use, or transfer byproduct material in accordance with the regulations in this chapter under the supervision of an authorized user as provided in § 35.38, unless prohibited by license condition.

§ 35.8 Information collection requirements: OMB approval.

(a) The Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). OMB has approved the information collection requirements in this part under control number 3150–

(b) The approved information collection requirements contained in this part appear in §§ 35.16, 35.17, 35.18, 35.30(c), 35.31(b), 35.32(a), 35.33(b), 35.34(c), 35.35(b), 35.36, 35.37(a)–(d), 35.50(e), 35.51(e), 35.53(c), 35.59 (d), (e), (g), and (i), 35.62, 35.63, 35.70(g), 35.80(f), 35.92(b), 35.204(c), 35.310, 35.315, 35.404(b), 35.406, 35.410(b), 35.606, 35.610, 35.621(e), 35.630(c), 35.632(g), 35.633 (e), and (j), 35.641(c), 35.642(c), 35.643(c), 35.644, and 35.645(c).

§ 35.15 Definitions.

"Agreement State" means any State with which the Commission or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended.

"ALARA" means as low as reasonably achievable.

"Area of use" means a portion of a physical structure that has been set aside for the purpose of receiving, using, or storing byproduct material.

"Authorized user" means a physician, dentist, or podiatrist who is identified as an authorized user on a Commission or Agreement State license that authorizes the medical use of byproduct material.

"Dentist" means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice dentistry on humans.

"Management" means the chief executive officer.

"Medical Institution" means an organization in which several medical disciplines are practiced.

"Medical use" means the intenational internal or external administration of byproduct material, or the radiation therefrom, to human beings in the practice of medicine in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

"Misadministration" means the administration of:

(1) A radiopharmaceutical or radiation from a sealed source other than the one intended;

(2) A radiopharmaceutical or radiation to the wrong patient;

(3) A radiopharmaceutical or radiation by a route of administration other than that intended by the prescribing physician;

(4) A diagnostic dosage of a radiopharmaceutical differing from the prescribed dosage by more than 50 percent;

(5) A therapeutic dosage of a radiopharmaceutical differing from the prescribed dosage by more than 10 percent; or

(6) A therapeutic radiation dose from a sealed source such that errors in the source calibration, time of exposure, and treatment geometry result in a calculated total treatment dose differing from the final prescribed total treatment dose by more than 10 percent.

"Mobile nuclear medicine service" means the transportation and medical use of byproduct material.

"Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

"Physician" means a medical doctor or doctor of osteopathy licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.

"Podiatrist" means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice podiatry on humans.

"Qualified teletherapy calibration expert" means the individual identified as the qualified teletherapy calibration expert on a Commission license.

"Radiation Safety Officer" means the individual identified as the Radiation Safety Officer on a Commission license.

"Sealed source" means any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material.

"Visiting authorized user" means an authorized user who is not identified on the license of the host.

§ 35.16 Application for license, amendment, or renewal.

(a) For use sited in a medical institution, only the institution's management may apply. For use not sited in a medical institution, any person may apply.

(b) An application for a license for medical use of byproduct material as described in §§ 35.100, 35.200, 35.300, 35.400, and 35.500 of this part must be made by filing an original and one copy of Form NRC–313, "Application for Materials License." For guidance in completing the form, refer to the instructions in Regulatory Guide 10.8 Revision 2, "Guide for the Preparation of Applications for Medical Programs." A request for a license amendment or renewal may be submitted as an original and one copy in letter format.

(c) An application for a license for medical use of byproduct material as described in § 35.600 of this part must be made by filing an original and one copy of Form NRC–313. For guidance in completing the form, refer to the instructions contained in Regulatory Guide 10.—, "Guide for the Preparation of Applications for Teletherapy Programs." A request for a license amendment or renewal may be submitted as an original and one copy in letter format.

(d) An applicant shall mail the completed request as directed below.

(1) If the applicant is a Federal agency in Region I or is located in Connecticut, the District of Columbia, Delaware, Maine, Massachusetts, New Jersey, Pennsylvania, or Vermont, it shall mail or deliver the completed application form to U.S. Nuclear Regulatory Commission, Region I, Material Licensing, 631 Park Avenue, King of Prussia, Pennsylvania 19406.

(2) If the applicant is a Federal agency in Region II or is located in Virginia, West Virginia, Puerto Rico, or the Virgin Islands, it shall mail or deliver the completed application form to U.S. Nuclear Regulatory Commission, Region II, Material Licensing Section, 101 Marietta Street, Suite 2900, Atlanta, Georgia 30323.

(3) If the applicant is a Federal agency in Region III or is located in Illinois, Indiana, Iowa, Michigan, Minnesota, Missouri, Ohio, or Wisconsin, it shall mail or deliver the completed application form to U.S. Nuclear Regulatory Commission, Region III, Material Licensing Section, 799 Roosevelt Road, Glen Ellyn, Illinois 60137.

(4) If the applicant is a Federal agency in Region IV or is located in Oklahoma, Montana, South Dakota, or Wyoming, it shall mail or deliver the completed application form to U.S. Nuclear Regulatory Commission, Region IV, Material Licensing Section, 611 Ryan Plaza Drive, Suite 1000, Arlington, Texas 76011.

(5) If the applicant is a Federal agency in Region V or is located in Alaska, Hawaii, or Guam, it shall mail or deliver the completed application form to U.S. Nuclear Regulatory Commission, Region V, Material Licensing Section, 1450 Maria Lane, Suite 210, Walnut Creek, California 94596.

(e) If the applicant is located in a State, territory, or possession that is not mentioned in paragraphs (d) (1) through (5) of this section, it shall:

(1) Mail the completed application form to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, or

(2) Deliver the completed application form to the Commission offices at:

(i) 1717 H Street NW., Washington, DC, or

(ii) 7915 Eastern Avenue, Silver Spring, Maryland.

§ 35.17 License amendments.

A licensee shall apply for and must receive a license amendment:

(a) Before it uses byproduct material for a method or type of medical use not permitted by the license issued under this part;

(b) Before it permits anyone, except a visiting authorized user described in § 35.34, to work as an authorized user under the license;

(c) Before it changes Radiation Safety Officers or Qualified Teletherapy Calibration Experts;

(d) Before it receives byproduct material in excess of the amount authorized on the license; and

(e) Before it adds to or changes the location or locations of use or mailing address identified on the license.

§ 35.18 Notifications.

A licensee shall notify the Commission by letter within thirty days when an authorized user, Radiation Safety Officer, or Qualified Teletherapy Calibration Expert, permanently discontinues performance of duties under the license. It shall mail the report to the appropriate address identified in § 35.16.

§ 35.28 License issuance.

The Commission shall issue a license for the medical use of byproduct material for a term of five years if:

(a) The applicant has filed Form NRC-313 "Application for Materials License" in accordance with the instructions in § 35.16;

(b) The applicant has paid any applicable fee as provided in Part 170 of this chapter;

(c) The Commission finds the applicant equipped and committed to observe the safety standards established by the Commission for the protection of the public health and safety; and

(d) The applicant meets the requirements of Part 30 of this chapter.

§ 35.29 Specific exemptions.

The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security and are othewise in the public interest.

Subpart B—General Administrative Requirements

§ 35.30 ALARA program.

(a) Each medical institution licensee shall implement a program to maintain individual and collective dose equivalents as low as reasonably achievable.

(b) To satisfy the requirement of paragraph (a) of this section:

(1) Management, the Radiation Safety Officer, and all authorized users must participate in the establishment, implementation, and operation of the program as required by the regulations or requested by the Radiation Safety Committee.

(2) The program must include an annual review by the Radiation Safety Committee of the types and amounts of byproduct material used, occupational dose reports or summaries, and continuing education and training for all personnel who work with or in the vicinity of byproduct material. The purpose of the review is to ensure that individuals make every reasonable effort to maintain individual and collective occupational dose as low as reasonably achievable, taking into account the state of technology, and the cost of improvements in relation to benefits.

(c) A licensee shall retain a written description of the ALARA program for the duration of the license. The written description must include:

(1) A commitment by management to keep individual and collective occupational dose as low as reasonably achievable;

(2) A requirement that the Radiation Safety Officer brief management once each year on the byproduct material program;

(3) Personnel exposure investigational levels that, when exceeded, will initiate an investigation by the Radiation Safety Officer of the cause of the exposure; and

(4) Personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the Radiation Safety Officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability or recurrence.

§ 35.31 Radiation Safety Officer.

(a) A licensee shall appoint a Radiation Safety Officer responsible for implementing the radiation safety program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program.

(b) The Radiation Safety Officer shall:

(1) Investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, and disposals, and other deviations from approved radiation safety practice and implement corrective actions as necessary;

(2) Establish and implement written policy and procedures for:

(i) Authorizing the purchase of byproduct material;

(ii) Receiving and opening packages of byproduct material;

(iii) Storing byproduct material;

(iv) Keeping an inventory record of byproduct material;

(v) Using byproduct material safely;

(vi) Taking emergency action if control of byproduct material is lost;

(vii) Performing periodic radiation surveys;

(viii) Performing checks of survey instruments and other safety equipment;

(ix) Disposing of byproduct material;

(x) Training personnel who work in or frequent areas where byproduct material is used or stored;

(xi) Keeping a copy of all records and reports required by the Commission regulations, a copy of these regulations, a copy of each licensing request and license and amendments, and the written policy and procedures required by the regulations.

(3) For medical use not at a medical institution, approve or disapprove radiation safety program changes with the advice and consent of management; and

(4) For medical use at a medical institution, assist the Radiation Safety Committee in the performance of its duties.

§ 35.32 Radiation Safety Committee.

Each medical institution licensee shall establish a Radiation Safety Committee to oversee the use of byproduct material. Management may establish more than one committee to meet these responsibilities.

(a) Each Committee must meet the following administrative requirements:

(1) Membership must consist of at least three individuals and must include an authorized user of each type of use

permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. Other members may be included as the licensee deems appropriate.

(2) The Committee must meet a least quarterly.

(3) To establish a quorum and to conduct business, one-half of the Committee's membership must be present, including the Radiation Safety Officer and the management's representative.

(4) The minutes of each Radiation Safety Committee meeting must include:

(i) The date of the meeting;

(ii) Members present;

(iii) Members absent;

(iv) Summary of deliberations and discussions;

(v) Recommended actions and the numerical results of all ballots; and

(vi) ALARA program reviews described in § 35.30(b)(2).

(5) The Committee must provide each member with a copy of the meeting minutes, and retain one copy for the duration of the license.

(b) To oversee the use of licensed material, the Committee must:

(1) Be responsible for monitoring the institutional program to maintain individual and collective doses as low as reasonably achievable;

(2) Review, on the basis of safety and with regard to the training and experience standards in Subpart J of this part, and approve or disapprove any individual who is to be listed as an authorized user, the Radiation Safety Officer, or Qualified Teletherapy Calibration Expert before submitting a license application or request for amendment or renewal;

(3) Review on the basis of safety and approve or disapprove each proposed method of use of byproduct material;

(4) Review on the basis of safety, and approve with the advice and consent of the Radiation Safety Officer and the management representative, or disapprove procedures and radiation safety program changes;

(5) Review quarterly, with the assistance of the Radiation Safety Officer, occupational radiation exposure records of all personnel working with byproduct material;

(6) Review quarterly, with the assistance of the Radiation Safety Officer, all incidents involving byproduct material with respect to cause and subsequent actions taken;

(7) Review annually, with the assistance of the Radiation Safety Officer, the byproduct material program; and

(8) Establish a table of investigational levels for occupational dose that, when exceeded, will initiate investigations and considerations of action by the Radiation Safety Officer.

§ 35.33 Requirement for authority and statement of responsibilities.

(a) A licensee shall provide the Radiation Safety Officer, and at a medical institution the Radiation Safety Committee, sufficient authority and organizational freedom to:

(1) Identify radiation safety problems;

(2) Initiate, recommend, or provide solutions; and

(3) Verify implementation of solutions.

(b) A licensee shall establish in writing the authorities, duties, responsibilities, and radiation safety activities of the Radiation Safety Officer, and at a medical institution the Radiation Safety Committee.

§ 35.34 Visiting authorized user.

(a) A licensee may permit any visiting authorized user to use licensed material for medical use under the terms of the licensee's license for sixty days each year if:

(1) The visiting authorized user has the prior written permission of the licensee's management and, if the use occurs on behalf of an institution, the institution's Radiation Safety Committee;

(2) The licensee has a copy of a Commission or Agreement State license that identifies the visiting authorized user by name as an authorized user for medical use; and

(3) Only those procedures for which the visiting authorized user is specifically authorized by a Commission or Agreement State license are performed by that individual.

(b) A licensee need not apply for a license amendment in order to permit a visiting authorized user to use licensed material as described in paragraph (a) of this section.

(c) A licensee shall retain copies of the records specified in this section for two years after the visiting authorized user's last use of licensed material unless the visiting authorized user has been listed as an authorized user on the licensee's license.

§ 35.35 Mobile nuclear medicine service administrative requirements.

(a) The Commission will only license mobile nuclear medicine service in accordance with Subparts D, E and H of this part and § 31.11 of this chapter to serve clients who do not have a Commission or Agreement State license for the materials listed in those Subparts.

(b) Mobile nuclear medicine service licensees shall retain for the duration of service a letter signed by the management of each location where services are rendered that authorizes use of byproduct material.

§ 35.36 Radiation safety program changes.

(a) A licensee may change the radiation safety procedures and equipment that are used to meet regulatory requirements and that were described in the application for license, renewal, or amendment. The licensee may also receive, use, and store licensed material (except teletherapy sources) in areas of use that were not identified in the application for license, renewal, or amendment.

(b) A licensee shall retain for the duration of the license a record of each change. The record must include the effective date of the change, a copy of the old and new radiation safety procedures, equipment descriptions, or area floor plans, the reason for the change, a summary of radiation safety matters that were considered before making the change, the signature of the Radiation Safety Officer, and the signatures of the affected authorized users and of management or, in a medical institution, the Radiation Safety Committee's chairman and the management representative.

§ 35.37 Records and reports of misadministrations.

(a) When a misadministration involves any therapy procedure, the licensee shall notify by telephone the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter The licensee shall also notify the referring physician of the affected patient and the patient or a responsible relative (or guardian), unless the referring physician agrees to inform the patient or believes, based on medical judgment, that telling the patient or the patient's responsible relative (or guardian) would be harmful to one or the other, respectively. These notifications must be made within 24 hours after the licensee discovers the misadministration. If the referring physician, patient, or the patient's responsible relative or guardian cannot be reached within 24 hours, the licensee shall notify them as soon as practicable. The licensee is not required to notify the patient or the patient's responsible relative or guardian without first consulting the referring physician; however, the licensee shall not delay medical care for the patient because of this.

(b) Within 15 days after an initial therapy misadministration report to NRC, the licensee shall report, in writing, to the NRC Regional Office initially telephoned and to the referring physician, and furnish a copy of the report to the patient or the patient's responsible relative (or guardian) if either was previously notified by the licensee under paragraph (a) of this section. The written report must include the licensee's name; the referring physician's name; a brief description of the event; the effect on the patient; the action taken to prevent recurrence; whether the licensee informed the patient or the patient's responsible relative (or guardian), and if not, why not. The report must not include the patient's name or other information that could lead to identification of the patient.

(c) When a misadministration involves a diagnostic procedure, the licensee shall notify, in writing, the referring physician and the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter. Licensee reports of diagnostic misadministrations are due within 10 days after the end of the calendar quarters (defined by March, June, September and December) in which they occur. These written reports must include the licensee's name; the referring physician's name; a description of the event; the effect on the patient; and the action taken to prevent recurrence. The report should not include the patient's name or other information that could lead to identification of the patient.

(d) Each licensee shall retain for ten years a record of each misadministration. The record must contain the names of all individuals involved in the event (including the physician, allied health personnel, the patient, and the patient's referring physican), the patient's social security number, a brief description of the event, the effect on the patient, and the action taken to prevent recurrence.

(e) Aside from the notification requirement, nothing in this section shall affect any rights or duties of licensees and physicians in relation to each other, patients, or responsible relatives (or guardians).

§ 35.38 Supervision.

A licensee who permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user as allowed by § 35.2(b) shall:

(a)(1) Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of byproduct material;

(2) Review the supervised individual's use of byproduct material and the records kept to reflect this use;

(3) Require the authorized user to be immediately available by telephone to the supervised individual; and

(4) Require the authorized user to be able to be physically present and available to the supervised individual on one hour's notice. The supervising authorized user need not be present for each use of byproduct material.

(b) Require the supervised individual receiving, possessing, using or transferring byproduct material under § 35.2(b) to:

(1) Follow the instructions of the supervising authorized user;

(2) Follow the procedures established by the Radiation Safety Officer; and

(3) Comply with the regulations of this part and the license conditions with respect to the use of byproduct material.

§ 35.49 Suppliers.

A licensee may use for medical use only:

(a) Byproduct material manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to the regulations in Part 30 and § 32.72, 32.73, or 32.74 of this chapter or the equivalent regulations of an Agreement State;

(b) Reagent kits that have been manufactured, labeled, packaged, and distributed in accordance with an approval by the Commission pursuant to § 32.73 or an Agreement State under equivalent regulations for the preparation of radiopharmaceuticals for medical use; and

(c) Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to Part 30 of this chapter or the equivalent regulations of an Agreement State.

Subpart C—General Technical Requirements

§ 35.50 Possession, use, calibration, and check of dose calibrators.

(a) A medical use licensee authorized to administer radiopharmaceuticals shall have in its possession a dose calibrator and use it to measure the amount of activity administered to each patient.

(b) A licensee shall:

(1) Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. To satisfy the requirement of this paragraph, the check must be done on a frequently used setting with a sealed source of not less than 10 microcuries of radium-226 or 50 microcuries of any other photon-emiyting radionuclide;

(2) Test each dose calibrator for accuracy upon installation and at least annually thereafter by assaying at least two sealed sources containing different radionuclides whose activity the manufacturer has determined within 5 percent of its stated activity, whose activity is at least 10 microcuries for radium-226 and 50 microcuries for any other photon-emitting radionuclide, and at least one of which has a principal photon energy between 100 keV and 500 keV;

(3) Test each dose calibrator for linearity upon installation and at least quarterly thereafter over the range of its use between the highest dosage that will be administered and 10 microcuries; and

(4) Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator.

(c) A licensee shall also perform appropriate checks and tests required by this section following adjustment or repair of the dose calibrator.

(d) A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

(e) A licensee shall retain a record of each check and test required by this section for two years unless directed otherwise. The records required in paragraphs (b)(1) through (b)(4) of this section must include:

(1) For paragraph (b)(1), the model and serial number of the dose calibrator, the identity of the radionuclide contained in the check source, the date of the check, the activity measured, and the initials of the individual who performed the check;

(2) For paragraph (b)(2), the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, and the signature of the Radiation Safety Officer;

(3) For paragraph (b)(3), the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, and the signature of the Radiation Safety Officer; and

(4) For paragraph (b)(4), the model and serial number of the dose calibrator, the configuration of the source measured, the activity measured for

each volume measured, the date of the test, and the signature of the Radiation Safety Officer.

§ 35.51 Calibration and check of survey instruments.

(a) A licensee shall calibrate the survey instruments used to show compliance with this part before first use, annually, and following repair.

(b) To satisfy the requirements of paragraph (a) of this section, the licensee shall:

(1) Calibrate all scale readings up to 1000 milliroentgens per hour with a radiation source;

(2) Calibrate two readings on each scale that must be calibrated; and

(3) Conspicuously note on the instrument the apparent exposure rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

(c) To satisfy the requirements of paragraph (b) of this section, the licensee shall:

(1) Consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 10 percent; and

(2) Consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent if a correction chart or graph is conspicuously attached to the instrument.

(d) A licensee shall check each survey instrument for proper operation with the dedicated check source before and after each use. The licensee is not required to keep records of these checks.

(e) The licensee shall retain a record of each calibration required in paragraph (a) of this section for two years. To satisfy the requirements of this paragraph, the record must include:

(1) A description of the calibration procedure; and

(2) A description of the source used and the certified exposure rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, and the signature of the individual who performed the calibration.

§ 35.53 Measurement of radiopharmaceutical dosages.

A licensee shall:

(a) Assay before medical use the activity of each radiopharmaceutical dosage that contains more than 10 microcuries of a photon-emitting radionuclide;

(b) Assay before medical use the activity of each radiopharmaceutical dosage with a desired activity of 10 microcuries or less of a photon-emitting radionuclide to verify that the dosage does not exceed 10 microcuries;

(c) Retain a record of the measurements required by this section for two years. To satisfy this requirement, the record must contain the:

(1) Generic name, trade name, or abreviation of the radiopharmaceutical, its lot number, and expiration dates and the radionuclide;

(2) Patient's name and identification number if one has been assigned;

(3) Prescribed dosage and activity of the dosage at the time of measurement, or a notation that the total activity is less than 10 microcuries;

(4) Date and time of the measurement; and

(5) Initials of the individual who made the measurement.

§ 35.58 Authorization for calibration and reference sources.

Any person authorized by § 35.2 for medical use of byproduct material may receive, possess, and use the following byproduct material for check, calibration, and reference use:

(a) Sealed sources manufactured and distributed by a person licensed pursuant to § 32.74 of this chapter or equivalent Agreement State regulations and that do not exceed 6 millicuries each;

(b) Any byproduct material listed in §§ 53.100 or 35.200 with a half-life not longer than 100 days in individual amounts not to exceed 15 millicuries;

(c) Any byproduct meterial listed in §§ 35.100 or 35.200 with a half-life longer than 100 days in individual amounts not to exceed 200 microcuries each; and

(d) Technetium-99m in individual amounts not to exceed 50 millicuries.

§ 35.59 Requirements for possession of sealed sources and brachytherapy sources.

(a) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer, and shall maintain the instructions for the duration of source use in a legible form convenient to users.

(b) A licensee in possession of a sealed source shall:

(1) Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within six months before transfer to the licensee; and

(2) Test the source for leakage at intervals not to exceed six months or at other intervals approved by the Commission or an Agreement State and described in the label or brochure that accompanies the source.

(c) To satisfy the leak test requirements of this section, the licensee must:

(1) Take a wipe sample from the sealed source or from the surfaces of the device in which the sealed source is mounted or stored on which radioactive contamination might be expected to accumulate or wash the source in a small volume of detergent solution and treat the entire volume as the sample;

(2) Take the teletheraphy source test sample when the source is in the "off" position; and

(3) Measure the sample so that the leakage test can detect the presence of 0.005 microcuries of radioactive material on the sample.

(d) A licensee shall retain leakage test records for two years. The records must contain the model number, and serial number if assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in microcuries, a description of the method used to measure each test sample, the date of the test, and the signature of the Radiation Safety Officer.

(e) If the leakage test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall:

(1) Immediately withdraw the sealed source from use and store it in accordance with the requirements in Parts 20 and 30 of this chapter; and

(2) File a report within five days of the leakage test with the appropriate Nuclear Regulatory Commission Regional Office listed in Appendix D of Part 20 of this chapter, with a copy to Director of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, describing the equipment involved, the test results, and the action taken.

(f) A licensee need not perform a leakage test on the following sources:

(1) Sources containing only byproduct material with a half-life of less than 30 days;

(2) Sources containing only byproduct materials as a gas;

(3) Sources containing 100 microcuries or less of beta or gammae-mitting material or 10 microcuries or less of alpha-emitting material;

(4) Sources stored and not being used. The licensee shall, however, test each such source for leakage before any use or transfer unless it has been leakage-tested within six months before the date of use or transfer; and

(5) Seeds of iridium-192 encased in nylon ribbon.

(g) A licensee in possession of a sealed source or brachytherapy source shall conduct a quarterly physical inventory of all such sources in its possession. The licensee shall retain each inventory record for five years. The inventory records must contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its estimated activity, the location of each source, and the signature of the Radiation Safety Officer.

(h) A licensee in possession of a sealed source or brachytherapy source shall survey with a low range survey meter quarterly all areas where such sources are stored. This does not apply to teletherapy sources in teletheraphy units or sealed sources in diagnostic devices.

(i) A licensee shall retain a record of each survey required in paragraph (h) of this section for two years. The record must include the date of the survey, a plan of each area that was surveyed, the measured exposure rate at several points in each area expressed in millirem per hour, the model number and serial number of the survey instrument used to make the survey, and the signature of the Radiation Safety Officer.

§ 35.60 Syringe shields.

(a) A licensee shall keep syringes that contain byproduct material to be administered in a radiation shield.

(b) A licensee shall require each individual who prepares a radiopharmaceutical kit to use a syringe radiation shield and shall require each individual who administers a radiopharmaceutical by injection to use a syringe radiation shield unless the use of the shield is contraindicated for that injection.

§ 35.61 Vial shields.

A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield.

§ 35.62 Syringe labels.

A licensee shall conspicuously label each syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical, with the radiopharmaceutical's abbreviation or with the type of diagnostic study or therapy procedure to be performed.

§ 35.63 Vial shield labels.

A licensee shall conspicuously label each vial radiation shield that contains a vial of a radiopharmaceutical with the radiopharmaceutical name or its abbreviation.

§ 35.70 Surveys for contamination and ambient radiation exposure rate.

(a) A licensee shall survey with a low range survey meter at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

(b) A licensee shall survey with a low range survey meter at least once each week all areas where radiopharmaceuticals or radiopharmaceutical waste is stored.

(c) A licensee shall conduct the surveys required by paragraphs (a) and (b) of this section so as to be able to measure exposure rates as low as 0.1 milliroentgen per hour.

(d) A licensee shall establish radiation exposure rate action levels for the surveys required by paragraphs (a) and (b) of this section and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if an exposure rate exceeds an action level.

(e) A licensee shall survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored.

(f) A licensee shall conduct the surveys required by paragraph (e) of this section so as to be able to detect contamination on each wipe sample of 200 disintegrations per minute.

(g) A licensee shall establish removable contamination action levels for the surveys required by paragraph (e) of this section and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds the action level.

(h) A licensee shall retain a record of each survey for two years. The record must include the date of the survey, a plan of each area surveyed, the action level established for each area, the measured exposure rate at several points in each area expressed in millirem per hour or disintegrations per minute, the model number of the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.

§ 35.75 Release of patients containing radiopharmaceuticals or permanent implants.

(a) A licensee may not authorize release from confinement for medical care any patient administered a radiopharmaceutical until either:

(1) The exposure rate from the patient is less than 6 milliroentgens per hour at a distance of one meter; or

(2) the activity in the patient is less than 30 millicuries.

(b) A licensee may not authorize release from confinement for medical care of any patient administered a permanent implant until the exposure rate from the patient is less than 6 milliroentgens per hour at a distance of one meter.

§ 35.80 Mobile nuclear medicine service technical requirements.

A licensee providing mobile nuclear medicine service shall:

(a) Transport to each location of use only syringes or vials containing prepared radiopharmaceuticals;

(b) Bring into each location of use all byproduct material to be used and, before leaving, remove all unused byproduct material and all associated waste;

(c) Secure or keep under constant surveillance and immediate control all byproduct material when in transit or at a location of use;

(d) Check survey instruments and dose calibrators as described in §§ 35.50 and 35.51, and check all other transported equipment for proper function before medical use at each location of use;

(e) Carry a calibrated survey meter in each vehicle that is being used to transport byproduct material, and, before leaving a client location of use, survey all radiopharmaceutical areas of use with a low range survey meter to ensure that all radiopharmaceuticals and all associated waste have been removed;

(f) Retain a record of each survey required in paragraph (e) of this section for two years. The record must include the date of the survey, a plan of each area that was surveyed, the measured exposure rate at several points in each area of use expressed in millirem per hour, the model number of the instrument used to make the survey, and the initials of the individual who performed the survey.

§ 35.90 Storage of volatiles and gases.

A licensee shall store volatile radiopharmaceuticals and radioactive gases in a fume hood or in a container with two barriers against release.

§ 35.92 Decay-in-storage.

(a) A licensee may hold byproduct material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash and is exempt from the requirements of § 20.301 of this chapter if it:

(1) Holds byproduct material for decay a minimum of ten half-lives;

(2) Monitors byproduct material at the container surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with a low range survey meter set on its most sesitive scale and with no interposed shielding;

(3) Removes or obliterates all radiation labels; and

(4) Separates and monitors each generator column individually with all radiation shielding removed to ensure that it has decayed to background radiation level before disposal.

(b) For paragraph (a) of this section, the licensee shall retain a record of each disposal for two years. The record must include the date of the disposal, the date on which the byproduct material was placed in storage, the model number of the survey instrument used, the background radiation exposure rate, the radiation exposure rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

Subpart D—Uptake, Dilution, and Excretion

§ 35.100 Use of radiopharmaceuticals for uptake, dilution and excretion studies.

(a) A licensee may use the following prepared radiopharmaceuticals for diagnostic studies involving the measurement of uptake, dilution, or excretion:

(1) Iodine-131 as sodium iodide, iodinated human serum albumin (IHSA), labeled rose bengal, or sodium iodohippurate;

(2) Iodine-125 as sodium iodide or iodinated human serum albumin (IHSA);

(3) Cobalt-58 as labeled cyanocobalamin;

(4) Cobalt-60 as labeled cyanocobalamin;

(5) Chromium-51 as sodium chromate or labeled human serum albumin;

(6) Iron-59 as citrate;

(7) Technetium-99m as pertechnetate;

(8) Any byproduct material in a radiopharmaceutical and for a diagnostic use involving measurements of uptake, dilution, or excretion for which the Food and Drug Administration (FDA) has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA).

(b) A licensee using a radiopharmaceutical listed in paragraph (a) of this section for a clinical procedure other than one specified in the product label or package insert instructions for use shall comply with the product label or package insert instructions regarding physical form, route of administration and dosage range.

§ 35.120 Possession of survey instrument.

A licensee authorized to use byproduct material for uptake, dilution, and excretion studies shall have in its possession a portable low level radiation survey instrument whose most sensitive scale has a full-scale deflection of not more than 1 milliroentgen per hour.

Subpart E—Imaging and Localization

§ 35.200 Use of radiopharmaceuticals, generators, and reagent kits for imaging and localization studies.

(a) A licensee may use the following radiopharmaceuticals, generators, and reagent kits for imaging and localization studies:

(1) Molybdenum-99/technetium-99m generators for the elution or extraction of technetium-99m as pertechnetate;

(2) Technetium-99m as pertechnetate;

(3) Prepared radiopharmaceuticals and reagent kits for the preparation of the following technetium-99m labeled radiopharmaceuticals:

(i) Sulfur colloid;

(ii) Pentetate sodium;

(iii) Human serum albumin microspheres;

(iv) Polyphosphate;

(v) Macroaggregated human serum albumin;

(vi) Etidronate sodium;

(vii) Stannous pyrophosphate;

(viii) Human serum albumin;

(ix) Medronate sodium;

(x) Gluceptate sodium;

(xi) Oxidronate sodium;

(xii) Disofenin; and

(xiii) Succimer.

(4) Iodine-131 as sodium iodide, iodinated human serum albumin, macroaggregated iodinated human serum albumin, colloidal (microaggregated) iodinated human serum albumin, rose bengal, or sodium iodohippurate;

(5) Iodine-125 as sodium iodide or fibrinogen;

(6) Chromium-51 as human serum albumin;

(7) Gold-198 in colloidal form;

(8) Mercury-197 as chlormerodrin;

(9) Selenium-75 as selenomethionine;

(10) Strontium-85 as nitrate;

(11) Ytterbium-169 as pentetate sodium;

(12) Xenon-133 as a gas or saline solution;

(13) Any byproduct material in a diagnostic radiopharmaceutical or any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing byproduct material for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA).

(b) A licensee using the radiopharmaceuticals listed in paragraph (a) of this section for clinical procedures other than those specified in the product label or package insert shall comply with the product label or package insert regarding physical form, route of administration, and dosage range.

(c) A licensee shall elute generators and prepare reagent kits in accordance with the manufacturer's instructions.

(d) The following radiopharmaceuticals, when used for the listed clinical procedures, are not subject to the restrictions in paragraph (b) of this section:

(1) Technetium-99m pentetate as an aerosol for lung function studies.

§ 35.204 Permissible molybdenum-99 concentration.

(a) A licensee may not administer to humans a radiopharmaceutical containing more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m.

(b) A licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators shall measure the molybdenum-99 concentration in each eluate or extract.

(c) A licensee who must measure molybdenum concentration shall retain a record of each measurement for two years. The record must include, for each elution or extraction of technetium-99m, the measured activity of the technetium expressed in millicuries, the measured activity of the molybdenum expressed in microcuries, the ratio of the measures expressed as microcuries of molybdenum per millicurie of technetium, the date of the test, and the initials of the individual who performed the test.

§ 35.205 Control of aerosols and gases.

(a) A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed by §§ 20.103 and 20.106 of this chapter.

(b) The system must either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

(c) A licensee shall only administer radioactive aerosols and gases in rooms that are at negative pressure compared to surrounding rooms.

(d) Before receiving, using, or storing a radioactive gas, the licensee shall calculate the amount of time needed after a spill to reduce the concentration in the area of use to the occupational limit listed in Appendix B to Part 20 of this chapter. The calculation must be based on the highest activity of gas handled in a single container and the measured available air exhaust rate.

(e) A licensee shall post the calculated time at the area of use and require that, in case of a gas spill, individuals evacuate the room until the posted time has elapsed.

(f) A licensee shall check the operation of collection and ventilation systems each six months.

§ 35.220 Possession of survey instruments.

A licensee authorized to use byproduct material for imaging and localization studies shall have in its possession a portable low level radiation survey instrument whose most sensitive scale has a full-scale deflection of not more than 1 milliroentgen per hour and a portable ion chamber radiation survey instrument that has a scale with a full-scale deflection of 1 roentgen per hour.

Subpart F—Radiopharmaceuticals for Therapy

§ 35.300 Use of radiopharmaceuticals for therapy.

A licensee may use the following prepared radiopharmaceuticals:

(a) Iodine-131 as iodide for treatment of hyperthyroidism, cardiac dysfunction, and thyroid carcinoma;

(b) Phosphorus-32 as soluble phosphate for treatment of polycythemia vera, leukemia, and bone metastases;

(c) Phosphorus-32 as colloidal chromic phosphate for intracavitary treatment of malignant effusions;

(d) Gold-198 as colloid for intracavitary treatment of malignant effusions;

(e) Any byproduct material in a radiopharmaceutical and for a therapeutic use for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND), or approved a "New Drug Application" (NDA).

§ 35.310 Safety instruction.

(a) A licensee shall provide oral and written radiation safety instruction for all personnel caring for the patient undergoing radiopharmaceutical therapy. To satisfy this requirement, the instruction must describe the licensee's procedures for:

(1) Patient control;
(2) Visitor control;
(3) Contamination control;
(4) Waste control; and
(5) Notification of the Radiation Safety Officer in case of the patient's death or medical emergency.

(b) A licensee shall keep for two years a list of individuals receiving instruction required by paragraph (a) of this section, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.

§ 35.315 Safety precautions.

(a) A licensee shall provide each individual hospitalized for radiopharmaceutical therapy a private room with a private sanitary facility.

(b) A licensee shall notify the Radiation Safety Officer immediately if the patient dies or has a medical emergency.

(c) A licensee shall post the patient's door with a "Radioactive Materials" sign and note in the patient's chart where and how long visitors may stay in the patient's room.

(d) The authorized user and Radiation Safety Officer must specifically authorize visits by individuals under age 18 on a case-by-case basis.

(e) The licensee shall either monitor material and items removed from the patient's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a low range survey meter set on its most sensitive scale and with no interposed shielding, or handle them as radioactive waste.

(f) The licensee shall survey the patient's room and private sanitary facility for removable contamination before assigning another patient to the room. The room must not be reassigned until removable contamination is less than 200 disintegrations per minute per 100 square centimeters.

(g) Within three days after administering a therapeutic dosage of iodine-131, the licensee shall measure the thyroid burden of each individual who helped prepare or administer the dosage, and retain for the period required by § 20.401(c)(1) a record of each thyroid burden measurement, its date, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements.

§ 35.320 Possession of survey instruments.

A licensee authorized to use byproduct material for radiopharmaceutical therapy shall have in its possession a portable low level radiation survey instrument whose most sensitive scale has a full-scale deflection of not more than 1 milliroentgen per hour and a portable ion chamber radiation survey instrument that has a scale with a full scale deflection of 1 Roentgen per hour.

Subpart G—Sources for Brachytherapy

§ 35.400 Use of sources for brachytherapy.

A licensee shall use the following sources in accordance with the manufacturer's radiation safety and handling instructions:

(a) Cesium-137 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

(b) Cobalt-60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

(c) Gold-198 as a sealed source in seeds for interstitial treatment of cancer;

(d) Iridium-192 as seeds encased in nylon ribbon for interstitial treatment of cancer;

(e) Strontium-90 as a sealed source in an applicator for treatment of superficial eye conditions; and

(f) Iodine-125 as a sealed source in seeds for interstitial treatment of cancer.

§ 35.404 Release of patients treated with temporary implants.

(a) Immediately after removing the last temporary implant source from a patient, the licensee shall make a radiation survey of the patient to confirm that all sources have been removed. The licensee may not release from confinement for medical care a patient treated by temporary implant until all sources have been removed.

(b) A licensee shall retain a record of patient surveys for two years. Each record must include the date of the survey, the name of the patient, the exposure rate from the patient expressed as millirem per hour and measured within one meter of the patient, and the initials of the individual who made the survey.

§ 35.406 Brachytherapy sources inventory.

(a) Each time brachytherapy sources are returned to an area of storage from an area of use, the licensee shall immediately count the number returned to ensure that all sources taken from the storage area have been returned.

(b) A licensee shall make a record of brachytherapy source use which must include:

(1) The names of the individuals permitted to handle the sources.

(2) The number and activity of sources removed from storage, the room number of use or patient's name, the time and date they were removed from storage, the number and activity of the sources in storage after the removal, and the initials of the individual who removed the sources from storage;

(3) The number and activity of sources returned to storage, the room number of use or patient's name, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

(c) Immediately after implanting sources in a patient the licensee shall make a radiation survey of the patient and the area of use to confirm that no sources have been misplaced. The licensee shall make a record of each survey.

(d) A licensee shall retain the records required in paragraphs (b) and (c) of this section for two years.

§ 35.410 Safety instruction.

(a) The licensee shall provide oral and written radiation safety instruction to all personnel caring for the patient undergoing implant therapy. To satisfy this requirement, the instruction must describe:

(1) Size and appearance of the brachytherapy sources;

(2) Safe handling and shielding instructions in case of a dislodged source;

(3) Procedures for patient control;

(4) Procedures for visitor control; and

(5) Procedures for notification of the Radiation Safety Officer if the patient dies or has a medical emergency.

(b) A licensee shall retain for two years a record of individuals receiving instruction required by paragraph (a) of this section, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.

§ 35.415 Safety precautions.

(a) The licensee shall provide a private room to each individual hositalized for implant thereapy.

(b) The licensee shall notify the Radiation Safety Officer immediately if the patient dies or has a medical emergency.

(c) A licensee shall post the patient's door with a "Radioactive Materials" sign and note in the patient's chart where and how long visitors may stay in the patient's room.

(d) The authorized user and Radiation Safety Officer must specifically authorize visits by individuals under age 18 on a case-by-case basis.

§ 35.420 Possession of survey instrument.

A licensee authorized to use byproduct material for implant therapy shall have in its possession a portable ion chamber radiation survey instrument that has a scale with a full scale deflection of 1 Roentgen per hour.

Subpart H—Sealed Sources for Diagnosis

§ 35.500 Use of sealed sources for diagnosis.

A licensee shall use the following sealed sources in accordance with the manufacturer's radiation safety and handling instructions:

(a) Iodine-125 as a sealed source in a device for bone mineral analysis;

(b) Americium-241 as a sealed source in a device for bone mineral analysis; and

(c) Iodine-125 as a sealed source in a portable device for imaging.

§ 35.520 Availability of survey instrument.

A licensee authorized to use byproduct material as a sealed source for diagnostic purposes shall have available for use a portable low level radiation survey instrument whose most sensitive scale has a full-scale deflection of not more than 1 milliroentgen per hour or a portable ion chamber radiation survey instrument that has a scale with a full scale deflection of 1 Roentgen per hour. The instrument must have been calibrated in accordance with § 35.51 of this part.

Subpart I—Teletherapy

§ 35.600 Use of a sealed source in a teletherapy unit.

The regulations and provisions of this subpart govern the use of teletherapy units for medical use that contain the following sources.

(a) Cobalt-60 as a sealed source; and

(b) Cesium-137 as a sealed source.

§ 35.605 Maintenance and repair restrictions.

Only a person specifically licensed by the Commission or an Agreement State to perform teletherapy unit maintenance and repair shall install, relocate, or remove a teletherapy sealed source or a teletherapy unit that contains a sealed source or maintain, adjust, or repair the source drawer, the shutter or other mechanism of a teletherapy unit that could expose the source, reduce the shielding around the source, or result in increased radiation levels.

§ 35.606 Amendments.

A licensee shall apply for and must receive a license amendment before:

(a) Making any change in the treatment room shielding;

(b) Making any change in the location of the teletherapy unit within the treatment room;

(c) Using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room;

(d) Relocating the teletherapy unit; or

(e) Allowing and individual not listed on the licensee's license to perform the duties of the qualified teletherapy calibration expert.

§ 35.610 Safety instruction.

(a) A licensee shall post written instructions at the teletherapy unit console. To satisfy this requirement, these instructions must inform the operator of:

(1) The procedure to be followed to ensure that only the patient is in the treatment room before turning the primary beam of radiation on to begin a treatment or after a door interlock interruption;

(2) The procedure to be followed if:

(i) The operator is unable to turn the primary beam of radiation off with controls outside the treatment room or any other abnormal operation occurs; and

(ii) The names and telephone numbers of the authorized users and Radiation Safety Officer to be immediately contacted if the teletherapy unit or console operates abnormally.

(b) A licensee shall provide instruction in the topics identified in paragraph (a) of this section to all individuals who operate a teletherapy unit.

(c) A licensee shall retain for two years a record of individuals receiving instruction required by paragraph (b) of this section, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.

§ 35.615 Doors, interlocks, and warning systems.

(a) A licensee shall control access to the teletherapy room by a door at each entrance.

(b) A licensee shall equip each entrance to the teletherapy room with an electrical interlock system that will:

(1) Prevent the operator from turning the primary beam of radiation on unless each treatment room entrance door is closed;

(2) Turn the primary beam of radiation off immediately when an entrance door is opened; and

(3) Prevent the primary beam of radiation from being turned on following an interlock interruption until all treatment room entrance doors are closed and the beam on-off control is reset at the console.

(c) A licensee shall equip each entrance to the teletherapy room with a beam condition indicator light.

§ 35.620 Possession of survey instrument.

A licensee authorized to use byproduct material in a teletherapy unit shall have in its possession either a portable low level radiation survey instrument whose most sensitive scale has a full-scale deflection of not more than 1 milliroentgen per hour or a portable ion chamber radiation survey instrument that has a scale with a full scale deflection of 1 Roentgen per hour.

§ 35.621 Radiation monitoring device.

(a) A licensee shall install in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status.

(b) Each radiation monitor must be capable of providing visible notice of a teletherapy unit malfunction that results in an exposed or partially exposed source. The visible indicator of high radiation levels must be observable by an individual entering the teletherapy room.

(c) Each radiation monitor must be equipped with an emergency power supply separate from the power supply to the teletherapy unit. This emergency power supply may be a battery system.

(d) Each radiation monitor must be checked for proper operation each day before the teletherapy unit is used for treatment of patients.

(e) A licensee shall maintain a record of the check required by paragraph (d) of this section for two years. The record must include the date of the check, notation that the monitor indicates when the source is and is not exposed, and the initials of the individual who performed the check.

(f) If a radiation monitor is inoperable for any reason, the licensee shall require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The instrument or dosimeter must be checked for proper operation at the beginning of each day of use.

(g) A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

§ 35.622 Viewing system.

A licensee shall construct or equip each teletherapy room to permit continuous observation of the patient from the teletherapy unit console during irradiation.

§ 35.630 Dosimetry equipment.

(a) A licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met.

(1) The system must have been calibrated by the National Bureau of Standards or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous two years and after any servicing that may have affected system calibration; or

(2) The system must have been calibrated within the previous four years; eighteen to thirty months after that calibration, the system must have been intercompared at an intercomparison meeting with another dosimetry system that was calibrated within the past twenty-four months by the National Bureau of Standards or by a calibration laboratory accredited by the AAPM. The intercomparison meeting must be sanctioned by a calibration laboratory or radiologic physics center accredited by the AAPM. The results of the intercomparison meeting must have indicated that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating cobalt-60 teletherapy units, the licensee shall use a teletherapy unit with a cobalt-60 source. When intercomparing dosimetry systems to be used for calibrating cesium-137 teletherapy units, the licensee shall use a teletherapy unit with a cesium-137 source.

(b) The licensee shall have available for use a dosimetry system for spot-check measurements. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with paragraph (a) of this section. This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in paragraph (a) of this section.

(c) The licensee shall retain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record must include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by paragraphs (a) and (b) of this section, the correction factors that were deduced, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by AAPM.

§ 35.632 Full calibration measurements.

(a) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

(1) Before the first medical use of the unit; and

(2) Before medical use under the following conditions:

(i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) Following replacement of the source or following reinstallation of the teletherapy unit in a new location;

(iii) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding one year.

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include determination of:

(1) The output within ±3 percent for the range of field sizes and for the distance or range of distances used for medical use;

(2) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(3) The uniformity of the radiation field and its dependence on the orientation of the useful beam;

(4) Timer accuracy;

(5) On-off error; and

(6) The accuracy of all distance measuring and localization devices in medical use.

(c) A licensee shall use the dosimetry system described in § 35.630(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (b)(1) of this section may then be made using dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with either the procedures recommended by the Scientific Committee on Radiation Dosimetry of the American Association of Physicists in Medicine that are described in *Physics in Medicine and Biology* Vol. 16, No. 3, 1971, pp. 379–396, or by Task Group 21 of the Radiation Therapy Committee of the American Association of Physicists in Medicine that are described in *Medical Physics* Vol. 10, No. 6, 1983, pp. 741–771. Both of these references have been approved for incorporation by reference by the Director of the Federal Register. Copies of the documents are available for inspection or may be obtained from the U.S. Nuclear Regulatory Commission, Public Document Room, 1717 H Street NW., Washington, DC 20555. Copies of the documents are also on file at the Office of the Federal Register, 1100 L Street NW., Room 8401, Washington, DC. A notice of any change in the material will be published in the **Federal Register**.

(e) A licensee shall correct mathematically the outputs determined in paragraph (b)(1) of this section for physical decay for intervals not exceeding one month.

(f) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (e) of this section must be performed by a qualified teletherapy calibration expert.

(g) A licensee shall retain a record of each calibration for the duration of the license. The record must include the date of the calibration, the manufacturer's name, model number, and serial number for both the teletherapy unit and the source, the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit, tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the measured timer accuracy for a typical treatment time, the calculated on-off error, the estimated accuracy of each distance measuring or localization device, and the signature of the qualified teletherapy calibration expert.

§ 35.633 Periodic spot-checks.

(a) A licensee authorized to use teletherapy units for medical use shall perform spot-checks on each teletherapy unit once in each calendar month.

(b) To satisfy the requirement of paragraph (a) of this section, measurements must include determination of:

(1) Timer accuracy;

(2) On-off error;

(3) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(4) The accuracy of all distance measuring and localization devices used for medical use;

(5) The output for one typical set of operating conditions; and

(6) The difference between the measurement made in paragraph (b)(5) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

(c) A licensee shall use the dosimetry system decribed in § 35.630(b) to make the measurement required in paragraph (b)(5) of this section.

(d) A licensee shall perform measurements required by paragraph (a) of this section in accordance with procedures established by the qualified teletherapy calibration expert. That individual need not actually perform the spot-check measurements.

(e) A licensee shall have the qualified teletherapy calibration expert review the results of each spot-check within 15 days. The qualified teletherapy calibration expert shall promptly notify the licensee in writing of the results of each spot-check. The licensee shall keep a copy of each written notification for two years.

(f) A licensee authorized to use a teletherapy unit for medical use shall perform spot-checks of each teletherapy facility once in each calendar month.

(g) To satisfy the requirement of paragraph (f) of this section, checks must assure proper operation of:

(1) Electrical interlocks at each teletherapy room entrance;

(2) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);

(3) Beam condition indicator lights on the teletherapy unit, on the control console, and in the facility;

(4) Viewing systems;

(5) Treatment room doors from inside and outside the treatment room; and

(6) Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

(h) A licensee shall lock the control console in the off position if any door interlock malfunctions. The licensee may not use the unit until the interlock system is repaired.

(i) A licensee shall promptly repair any system identified in paragraph (g) of this section that is not operating properly.

(j) A licensee shall retain a record of each spot-check required by paragraphs (a) and (f) of this section for two years. The record must include the date of the spot-check, the manufacturer's names, model number, and serial number for both the teletherapy unit and source, the manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit, the measured timer accuracy, the calculated on-off error, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the measured timer accuracy for a typical treatment time, the calculated on-off error, the estimated accuracy of each distance measuring or localization device, the difference between the anticipated output and the measured output, notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors, and the signature of the individual who performed the periodic spot-check.

§ 35.641 Radiation surveys for teletherapy facilities.

(a) Before medical use, after each installation of a teletherapy source, and after making any change for which an amendment is required by § 35.606(a)–(d), the licensee shall perform radiation surveys to verify that:

(1) The maximum and average radiation levels at one meter from the teletherapy source with the source in the off position and the collimators set for a normal treatment field do not exceed 10 milliroentgens per hour and 2 milliroentgens per hour, respectively; and

(2) With the teletherapy source in the on position with the largest clinically available treatment field and with a scattering phantom in the primary beam of radiation, that:

(i) Radiation quantities in restricted areas adjacent to the treatment room are not likely to cause personnel exposures in excess of the limits specified in § 20.101 of this chapter; and

(ii) Radiation quantities in unrestricted areas adjacent to the treatment room do not exceed the limits specified in § 20.105(b) of this chapter.

(b) If the results of the surveys required in paragraph (a) of this section indicate any radiation quantity in excess of the respective limit specified in that paragraph, the licensee shall lock the control in the off position and not use the unit:

(1) Except as may be necessary to repair, replace, or test the teletherapy unit shielding or the treatment room shielding; or

(2) Until the licensee has received a specific exemption pursuant to § 20.501 of this chapter.

(c) A licensee shall retain a record of the radiation measurements made following installation of a source for the duration of the license. The record must include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the teletherapy unit, the source, and the instrument used to measure radiation levels, each dose rate measured around the teletherapy source while in the off position and the average of all measurements, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in millirem per hour, the calculated maximum quantity of radiation over a period of one week for each restricted and unrestricted area, and the signature of the Radiation Safety Officer.

§ 35.642 Safety checks for teletherapy facilities.

(a) A licensee shall promptly check all systems listed in § 35.633(g) for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by § 35.606(a)–(d).

(b) If the results of the checks required in paragraph (a) of this section indicate the malfunction of any system specified in § 35.633(g), the licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(c) A licensee shall retain for two years a record of the facility checks following installation of a source. The record must include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, and doors, and the signature of the Radiation Safety Officer.

§ 35.643 Modification of teletherapy unit or room before beginning a treatment program.

If the survey required by § 35.641 indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by § 20.105(b) of this chapter, before beginning the treatment program the licensee shall:

(a) Either equip the unit with stops or add additional radiation shielding to ensure compliance with § 20.105(b);

(b) Perform the survey required by § 35.641 again; and

(c) Include in the report required by § 35.644 the results of the initial survey, a description of the modification made to comply with paragraph (a) of this section, and the results of the second survey; or

(d) Request and receive a license amendment under § 20.105(a) of this part that authorizes radiation levels in unrestricted areas greater than those permitted by § 20.105(b).

§ 35.644 Reports of teletherapy surveys, checks, tests, and measurements.

A licensee shall mail an original and a copy of the records required in §§ 35.641, 35.642, 35.643, and the output from the teletherapy source expressed as Roentgens per hour at a distance of one meter from the source and determined during the full calibration required in § 35.632, to the appropriate Commission Regional Office listed in § 35.16 of this part within thirty days following completion of the action that initiated the record requirement.

§ 35.645 Five-year inspection.

(a) A licensee shall have each teletherapy unit fully inspected and serviced during teletherapy source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(b) This inspection and servicing may only be performed by persons specifically licensed to do so by the Commission or an Agreement State.

(c) A licensee shall keep a record of the inspection and servicing for the duration of the license. The record must contain the inspector's name, the inspector's license number, the date of inspection, the manufacturer's name and model number and serial number for both the teletherapy unit and source, a list of components inspected, a list of components serviced and the type of service, a list of components replaced, and the signature of the inspector.

(d) Amendment to teletherapy licenses that extended the time interval for the inspection and servicing requirement of paragraph (a) of this section that were in effect on March 4, 1983 remain in effect and are not rescinded by this section.

Subpart J—Training and Experience Requirements

§ 35.900 Radiation Safety Officer.

Except as provided in § 35.901, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in § 35.32 to:

(a) Be certified by:

(1) American Board of Health Physics in Comprehensive Health Physics;

(2) American Board of Radiology in Radiological Physics, Therapeutic Radiological Physics, or Medical Nuclear Physics; or

(3) American Board of Nuclear Medicine Science in Nuclear Medicine Science; or

(b) Have had 200 hours of classroom and laboratory training and one year of experience as follows:

(1) 100 hours of radiation physics and instrumentation;

(2) 30 hours of radiation protection;

(3) 20 hours of mathematics pertaining to the use and measurement of radioactivity;

(4) 20 hours of radiation biology;

(5) 30 hours of radiopharmaceutical chemistry; and

(6) One year of full time experience in radiation safety at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on a Commission or Agreement State license that authorizes the medical use of byproduct material; or

(c) Be an authorized user for those byproduct material uses that come within the Radiation Safety Officer's responsibilities.

§ 35.901 Training for experienced Radiation Safety Officer.

An individual identified as a Radiation Safety Officer on a Commission or Agreement State license on [*insert effective date of final rule*] who oversees only the use of byproduct material for which the licensee was authorized on that date need not comply with the training requirements of § 35.900.

§ 35.910 Training for uptake, dilution, and excretion studies.

Except as provided in §§ 35.970 and 35.971, the licensee shall require the authorized user of a radiopharmaceutical listed in § 35.100(a) to be a physician who:

(a) Is certified in:

(1) Nuclear medicine by the American Board of Nuclear Medicine;

(2) Diagnostic radiology with special competence in nuclear radiology by the American Board of Radiology; or

(3) Diagnostic radiology or radiology within the previous five years by the American Osteopathic Board of Radiology; or

(b) Has completed 80 hours of instruction in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, and 40 hours of supervised clinical experience.

(1) To satisfy the basic instruction requirement, the classroom and laboratory instruction must include:

(i) 25 hours of radiation physics and instrumentation;

(ii) 25 hours of radiation protection;

(iii) 10 hours of mathematics pertaining to the use and measurement of radioactivity;

(iv) 10 hours of radiation biology; and

(v) 10 hours of radiopharmaceutical chemistry.

(2) To satisfy the requirement for supervised clinical experience, training must be under the supervision of an authorized user at a medical institution and must include:

(i) Examining patients and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

(ii) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

(iii) Administering dosages to patients and using syringe radiation shields;

(iv) Collaborating with the authorized user in the interpretation of radioisotope test results; and

(v) Patient followup; or

(c) Has successfully completed a six-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in paragraph (b) of this section.

§ 35.920 Training for imaging and localization studies.

Except as provided in § 35.970 or 35.971, the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit listed in § 35.200(a) to be a physician who:

(a) Is certified in:

(1) Nuclear medicine by the American Board of Nuclear Medicine;

(2) Diagnostic radiology with special competence in nuclear radiology by the American Board of Radiology; or

(3) Diagnostic radiology or radiology within the previous five years by the American Osteopathic Board of Radiology; or

(b) Has completed 200 hours of instruction in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, 500 hours of supervised work experience and 500 hours of supervised clinical experience.

(1) To satisfy the basic instruction requirement, the classroom and laboratory training must include:

(i) 100 hours of radiation physics and instrumentation;

(ii) 30 hours of radiation protection;

(iii) 20 hours of mathematics pertaining to the use and measurement of radioactivity;

(iv) 30 hours of radiopharmaceutical chemistry; and

(v) 20 hours of radiation biology.

(2) To satisfy the requirement for supervised work experience, training must be under the supervision of an authorized user at a medical institution and must include:

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;

(iii) Calculating and safely preparing patient dosages;

(iv) Using administrative controls to prevent the misadministration of byproduct material;

(v) Using emergency procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(vi) Eluting technetium-99m from generator systems, assaying and testing the eluate for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals.

(3) To satisfy the requirement for supervised clinical experience, training must be under the supervision of an authorized user at a medical institution and must include:

(i) Examining patients and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

(ii) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

(iii) Administering dosages to patients and using syringe radiation shields;

(iv) Collaborating with the authorized user in the interpretation of radioisotope test results; and

(v) Patient followup; or

(c) Has successfully completed a six-month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in paragraph (b) of this section.

§ 35.930 Training for therapeutic use of radiopharmaceuticals.

Except as provided in § 35.970, the licensee shall require the authorized user of a radiopharmaceutical listed in § 35.300 for therapy to be a physician who:

(a) Is certified in nuclear medicine by the American Board of Nuclear Medicine; or

(b) Has completed 80 hours of instruction in basic radioisotope handling techniques applicable to the use of therapeutic radiopharmaceuticals, and has had supervised clinical experience.

(1) To satisfy the requirement for instruction, the classroom and laboratory training must include:

(i)

(i) 25 hours of radiation physics and instrumentation;

(ii) 25 hours of radiation protection;

(iii) 10 hours of mathematics pertaining to the use and measurement of radioactivity; and

(iv) 20 hours of radiation biology;

(2) To satisfy the requirement for supervised clinical experience, training must be under the supervision of an authorized user at a medical institution and must include:

(i) Use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in 10 individuals;

(ii) Use of soluble phosphorus-32 for the treatment of polycythemia vera, leukemia, or bone metastases in 3 individuals;

(iii) Use of iodine-131 for treatment of thyroid carcinoma in 3 individuals; and

(iv) Use of colloidal chromic phosphorus-32 or of colloidal gold-198 for intracavitary treatment of malignant effusions in 3 individuals.

§ 35.940 Training for therapeutic use of brachytherapy sources.

Except as provided in § 35.970, the licensee shall require the authorized user using a brachytherapy source listed in § 35.400 for therapy to be a physician who:

(a) Is certified in:

(1) Radiology or therapeutic radiology by the American Board of Radiology:

(2) Radiation oncology by the American Osteopathic Board of Radiology:

(3) Radiology, with a specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology": or

(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons: or

(b) Is in the active practice of therapeutic radiology, has completed 200 hours of instruction in basic radioisotope handling techniques applicable to the therapeutic use of brachytherapy sources and 500 hours of supervised work experience and a minimum of three years of supervised clinical experience.

(1) To satisfy the requirement for instruction, the classroom and laboratory training must include:

(i) 110 hours of radiation physics and instrumentation:

(ii) 40 hours of radiation protection:

(iii) 25 hours of mathematics pertaining to the use and measurement of radioactivity: and

(iv) 25 hours of radiation biology

(2) To satisfy the requirement for supervised work experience, training must be under the supervision of an authorized user at an institution and must include:

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys:

(ii) Checking survey meters for proper operation:

(iii) Preparing, implanting, and removing sealed sources:

(iv) Using administrative controls to prevent the misadministration of byproduct material: and

(v) Using emergency procedures to control byproduct material.

(3) To satisfy the requirement for a period of supervised clinical experience, training must include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution. The supervised clinical experience must include:

(i) Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications:

(ii) Selecting the proper brachytherapy sources and dose and method of administration:

(iii) Calculating the dose: and

(iv) Post-administration followup and review of case histories in collaboration with the authorized user.

§ 35.941 Training for ophthalmic use of strontium-90.

Except as provided in § 35.970, the licensee shall require the authorized user using only strontium-90 ophthalmic radiotherapy to be a physician who:

(a) Is certified in radiology or therapeutic radiology by the American Board of Radiology: or

(b) Is in the active practice of therapeutic radiology or ophthalmology, and has completed 24 hours of instruction in basic radioisotope handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy.

(1) To satisfy the requirement for instruction, the classroom and laboratory training must include:

(i) 6 hours of radiation physics and instrumentation:

(ii) 6 hours of radiation protection:

(iii) 4 hours of mathematics pertaining to the use and measurement of radioactivity: and

(iv) 8 hours of radiation biology.

(2) To satisfy the requirement for a period of supervised clinical training in ophthalmic radiotherapy, training must be under the supervision of an authorized user at a medical institution and must include the use of strontium-90 for the ophthalmic treatment of five individuals that includes

(i) Examination of each individual to be treated:

(ii) Calculation of the dose to be administered:

(iii) Administration of the dose: and

(iv) Followup and review of each individual's case history.

§ 35.950 Training for use of sealed sources for diagnosis.

Except as provided in § 35.970, the licensee shall require the authorized user using a sealed source in a device listed in § 35.500 to be a physician, dentist, or podiatrist who:

(a) Is certified in

(1) Radiology, diagnostic radiology with special competence in nuclear radiology, or therapeutic radiology by the American Board of Radiology:

(2) Nuclear medicine by the American Board of Nuclear Medicine: or

(3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology: or

(b) Has completed 8 hours of instruction in basic radioisotope handling techniques specifically applicable to the use of the device. To satisfy the requirement for instruction, the training must include:

(1) 3 hours of radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation:

(2) 3 hours of radiation biology: and

(3) 2 hours of radiation protection and training in the use of the device for the purposes authorized by the license.

§ 35.960 Training for teletherapy.

Except as provided in § 35.970, the licensee shall require the authorized user using a sealed source listed in § 35.600 in a teletherapy unit to be a physician who:

(a) Is certified in:

(1) Radiology or therapeutic radiology by the American Board of Radiology:

(2) Radiation oncology by the American Osteopathic Board of Radiology:

(3) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology": or

(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons: or

(b) Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radioisotope techniques applicable to the use of a sealed source in a teletherapy unit, 500 hours of supervised work experience, and a minimum of three years of supervised clinical experience.

(1) To satisfy the requirement for instruction, the classroom and laboratory training must include:

(i) 110 hours of radiation physics and instrumentation:

(ii) 40 hours of radiation protection:

(iii) 25 hours of mathematics pertaining to the use and measurement of radioactivity: and

(iv) 25 hours of radiation biology.

(2) To satisfy the requirement for supervised work experience, training must be under the supervision of an authorized user at an institution and must include:

(i) Review of the full calibration measurements and periodic spot checks:

(ii) Preparing treatment plans and calculating treatment times:

(iii) Using administrative controls to prevent misadministrations:

(iv) Implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and

(v) Checking and using survey meters.

(3) To satisfy the requirement for a period of supervised clinical experience, training must include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution. The supervised clinical experience must include:

(i) Examining individuals and reviewing their case histories to determine their suitability for teletherapy treatment, and any limitations or contraindications;

(ii) Selecting the proper dose and how it is to be administered;

(iii) Calculating the teletherapy doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses as warranted by patients' reaction to radiation; and

(iv) Post-administration followup and review of case histories.

§ 35.961 Training for qualified teletherapy calibration expert.

The licensee shall require the qualified teletherapy calibration expert to:

(a) Be certified by the American Board of Radiology in:

(1) Therapeutic radiological physics;

(2) Roentgen ray and gamma ray physics;

(3) X-ray and radium physics; or

(4) Radiological physics; or

(b) Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed one year of full time training in therapeutic radiological physics and also one year of full time work experience under the supervision of a qualified teletherapy calibration expert at a medical institution. To satisfy this requirements, the neophyte qualified teletherapy calibration expert must have performed the tasks listed in §§ 35.59, 35.632, 35.633, and 35.641 of this part under the supervision of a qualified teletherapy calibration expert during the year of work experience.

§ 35.970 Training for experienced authorized users.

Physicians, dentists, or podiatrists identified as authorized users for the human use of byproduct material on a Commission or Agreement State license on [*insert effective date of final rule*] who perform only those methods of use for which they were authorized on that date need not comply with the training requirements of Subpart J.

§ 35.971 Physician training in a three month program.

A physician who, before July 1, 1984, began a three month nuclear medicine training program approved by the Accreditation Council for Graduate Medical Education and has successfully completed the program need not comply with requirements of §§ 35.910 or 35.920.

§ 35.972 Recentness of training.

The training and experience specified in this subpart must have been obtained within the five years preceding the date of application or the individual must have had continuing experience since the required training and experience was completed.

Subpart K—Enforcement

§ 35.990 Violations.

(a) An injunction or other court order may be obtained to prohibit a violation of any provision of:

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) Any rule, regulation, or order issued under these Acts.

(b) A court order may be obtained for the payment of a civil penalty imposed for violation of:

(1) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 under section 234 of the Atomic Energy Act of 1954;

(2) Section 206 of the Energy Reorganization Act of 1974;

(3) Any rule regulation, or order issued under these Acts;

(4) Any term condition, or limitation of any license issued under these Acts; or

(5) Any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954.

(c) Any person who willfully violates any provision of the Atomic Energy Act of 1954, as amended, or any rule, regulation, or order issued under the Act may be guilty of a crime and, upon conviction, may be punished by fine or imprisonment or both as provided by law. Regulations issued under the Act include regulations issued under section 161, and cited in the authority citation at the beginning of this part for the purposes of section 223.

§ 35.999 Resolution of conflicting requirements during transition period.

If the rules in this part conflict with the licensee's radiation safety program as identified in its license, and if that license was approved by the Commission before [*insert effective date of final rule*] and has not been renewed, then the requirements in the license will apply.

PART 30—RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

2. The authority citation for Part 30 continues to read as follows:

Authority: Sec. 161, as amended (42 U.S.C. 2201); sec. 201, as amended (42 U.S.C. 5481).

3. Section 30.4 is amended by revising paragraphs (h) and (l) to read as follows and by adding new paragraphs (y) and (z) as follows:

§ 30.4 Definitions.

* * * * *

(h) "Medical use" means the intentional internal or external administration of byproduct material, or the radiation therefrom, to human beings in the practice of medicine in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico in the practice of medicine.

* * * * *

(l) "Physician" means a medical doctor or doctor of osteopathy licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine;

* * * * *

(y) "Dentist" means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice dentistry on humans.

(z) "Podiatrist" means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice podiatry on humans.

4. Section 30.34 is amended by revising paragraph (g) to read as follows:

§ 30.34 Terms and conditions of licenses.

* * * * *

(g) A licensee may prepare technetium-99m radiopharmaceuticals only with technetium-99m that contains less than 0.15 microcuries of molybdenum-99 per millicurie of technetium-99m. The licensee shall perform tests and maintain the records required by § 35.204.

PART 31—GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

5. The authority citation for Part 31 continues to read as follows:

Authority: Sec. 161, as amended (42 U.S.C. 2201); sec. 201, as amended (42 U.S.C. 5481).

6. Section 31.11 is amended by revising paragraph (b) to read as follows:

§ 31.11 General license for use of byproduct material for certain in vitro clinical or laboratory testing.

* * * * *

(b) No person shall receive, acquire, possess, use, or transfer byproduct material pursuant to the general license established by paragraph (a) of this section unless that person:

(1) Has filed Form NRC–483, "Registration Certificate—In Vitro Testing with Byproduct Material Under General License," with the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555 and received from the Commission a validated copy of Form NRC–483 with a registration number assigned;

(2) Has a license that authorizes the medical use of byproduct material and that expires before [*insert five years after effective date of final rule*]; or

(3) Has a license that authorizes the medical use of byproduct material and also authorizes the use of byproduct material consistent with the requirements of this section.

* * * * *

PART 32—SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIALS

7. The authority citation for Part 32 continues to read as follows:

Authority: Sec. 161, as amended (42 U.S.C. 2201); sec. 201, as amended (42 U.S.C. 5481).

§ 32.70 [Removed]

8. Section 32.70 is removed.

9. In § 32.72 the introductory text of paragraph (a) and paragraph (a)(4)(i) are revised to read as follows:

§ 32.72 Manufacture and distribution of radiopharmaceuticals containing byproduct material for medical use under group licenses.

(a) An application for a specific license to manufacture and distribute radiopharmaceuticals containing byproduct material for use by persons authorized pursuant to Part 35 of this chapter will be approved if:

* * * * *

(4)(i) The label affixed to each package of the radiopharmaceutical contains information on the radionuclide, quantity, and date of assay, and the label, or the leaflet or brochure that accompanies each package, contains a statement that the radiopharmaceutical is licensed by the U.S. Nuclear Regulatory Commission for distribution to persons licensed to use byproduct material listed in §§ 35.100, 35.200, or 35.300, as appropriate, or under an equivalent license of an Agreement State.

* * * * *

10. In § 32.73 paragraph (a)(5)(ii) is revised to read as follows:

§ 32.73 Manufacture and distribution of generators or reagent kits for preparation of radiopharmaceuticals containing byproduct material.

(a) * * *

(5) * * *

(ii) A statement that this generator or reagent kit (as appropriate) is approved for distribution to persons licensed by the U.S. Nuclear Regulatory Commission to use byproduct material identified in § 35.200 or under an equivalent license of an Agreement State.

* * * * *

11. In § 32.74 the introductory text of paragraph (a) and paragraph (a)(3) are revised to read as follows:

§ 32.74 Manufacture and distribution of sources or devices containing byproduct material for medical use.

(a) An application for a specific license to manufacture and distribute sources and devices containing byproduct material to persons licensed pursuant to Part 35 of this chapter for use as a calibration or reference source or for the uses listed in §§ 35.400 and 35.500 of this chapter will be approved if:

* * * * *

(3) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity and date of assay, and a statement that the (name of source or device) is licensed by the U.S. Nuclear Regulatory Commission for distribution to persons licensed to use byproduct material identified in §§ 35.58, 35.400, or 35.500, as appropriate, or under an equivalent license of an Agreement State.

* * * * *

PART 40—DOMESTIC LICENSING OF SOURCE MATERIAL

12. The authority citation for Part 40 continues to read as follows:

Authority: Sec. 161, as amended (42 U.S.C. 2201); sec. 201, as amended (42 U.S.C. 5481).

13. Section 40.4 is amended by revising paragraph (g) to read as follows:

§ 40.4 Definitions.

* * * * *

(g) "Physician" means a medical doctor or doctor of osteopathy licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine;

* * * * *

Dated at Washington, D.C., this 22nd day of July 1985.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

UNITED STATES NUCLEAR REGULATORY COMMISSION
RULES and REGULATIONS

TITLE 10, CHAPTER 1, CODE OF FEDERAL REGULATIONS — ENERGY

PART 35
HUMAN USES OF BYPRODUCT MATERIAL

PETITIONS FOR RULE MAKING

44 FR 26817
Published 5/7/79
Comment period expires 7/6/79

George V. Taplin, M.D.; Filing of Petition for Rule Making

Notice is hereby given that Dr. George V. Taplin, Division of Nuclear Medicine, University of California, Los Angeles, California, has filed with the Nuclear Regulatory Commission a petition for rule making dated March 28, 1979, requesting the Commission to amend its regulation "Human Uses of Byproduct Material," 10 CFR Part 35.

On February 20, 1979 the Commission published in the *Federal Register* (44 FR 10358), effective March 22, 1979, amendments to its regulation 10 CFR Part 35, to permit physicians greater latitude, when they use certain low-risk diagnostic radiopharmaceuticals, by no longer designating the FDA authorized clinical procedures. However, the amendments require the physicians to follow the package insert regarding chemical and physical form, route of administration and dosage range when they perform clinical procedures that have not been approved by FDA. These restrictions do not apply if the physicians perform the FDA approved clinical procedures that are listed in the package insert.

The petitioner requests that the Commission reconsider and rescind the requirement that physicians must use an approved radiopharmaceutical strictly in accord with the manufacturers' package insert.

The petitioner states that:

> This change is in direct opposition to the current objectives of both the NRC and FDA which permit physicians to use approved drugs according to their best knowledge and judgment and in the interest of the patient. In my opinion this new regulation will hinder the development of new safe applications of approved drugs especially in the case of Technetium labeled DTPA and prevent its widespread use as a routine lung imaging agent in the diagnosis of pulmonary embolism.

The petitioner states also that:

> My specific disagreement with this new restriction is that it would preclude the use of Technetium 99m DTPA as an aerosol by inhalation for lung imaging. This application and route of administration provide the physician with additional useful medical information while exposing the patient to lower levels of radiation and from the approved applications for brain and kidney imaging wherein doses from 5 to 20 mCi per examination are administered intravenously
> * * *

Enclosed with the petition are reprints of two pertinent articles by Dr. George V. Taplin and Dr. Sawtantra K. Chopra.

A copy of the petition for rule making is available for public inspection in the Commission's Public Document Room, 1717 H Street, N.W., Washington, D.C. A copy of the petition may be obtained by writing the Division of Rules and Records at the below address.

All persons who desire to submit written comments or suggestions concerning the petition for rule making should send their comments to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Attention: Docketing and Service Branch by July 6, 1979.

For further information contact: Gerald L. Hutton, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone: 301-492-7086.

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47 FR 4311
Published 1/29/82

10 CFR Part 35

[Docket No. PRM-35-2]

Receipt of Petition for Rulemaking From the American Association of Physicists in Medicine

AGENCY: Nuclear Regulatory Commission.

ACTION: Publication of a petition for rulemaking.

SUMMARY: The Nuclear Regulatory Commission is publishing a petition for rulemaking submitted by the American Association of Physicists in Medicine. The petition requests an interval longer than the two years between required calibrations of a dosimetry system used to perform full calibration measurements on a teletherapy unit—as long as suitable dosimetry system verification checks are carried out. The suggested amendments are intended to reduce the current six month waiting period for instrument calibration without adversely affecting dosimetry system reliability.

DATE: Submit comments by March 30, 1982. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

ADDRESSES: Submit comments to: The Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, attention: Docketing and Service Branch.

Hand deliver comments to: Room 1121, 1717 H Street, NW., Washington, DC between 8:15 a.m. and 5:00 p.m.

For a copy of the petition write to: The Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

Inspect and copy comments received on the petition at: The NRC Public Document Room, 1717 H Street, NW., Washington, DC.

FOR FURTHER INFORMATION: J. M. Felton, Director, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: (301) 492-7211.

SUPPLEMENTARY INFORMATION: The Nuclear Regulatory Commission (NRC) received a petition for rulemaking from the American Association of Physicists in Medicine (AAPM). The petition has been assigned Docket No. PRM-35-2. The petition suggests amendments to §§ 35.23(a) and 35.25(a) that would permit an interval longer than two years between required calibrations of a dosimetry system that is used to perform calibration measurements of a teletherapy unit—as long as suitable dosimetry verification checks are carried out.

As an interim measure, the petition also recommends that a variance be granted to licensed teletherapy users who are unable to have instruments calibrated within the required period.

The current text of § 35.23(a) reads: "Full calibration measurements required by § 35.21 shall be performed using a dosimetry system that has been calibrated by the National Bureau of Standards or by a Regional Calibration Laboratory accredited by the American Association of Physicists in Medicine. The dosimetry system shall have been calibrated within the previous two years and after any servicing that may have affected system calibration."

The petitioner contends that: "The National Bureau of Standards (NBS) and the accredited Regional Calibration Laboratories (RCLs) are able to calibrate a limited number of instruments each year. With the advent of the referenced (§ 35.21) NRC regulation the waiting period for instrument calibration has increased and at present is about six months. It is probable that the waiting period will become longer as more instruments are due for calibrations."

To alleviate this situation, the petitioner recommends that the NRC revise 10 CFR 35.23(a) and 35.25(a) to permit a longer interval between required calibrations. In addition, the petitioner recommends, as an interim measure while the suggested amendments are under consideration, that the NRC grant a variance to a licensed teletherapy user who is not able to have instruments calibrated within the two year period. The suggested revisions to §§ 35.23(a) and 35.25(a) read as follows:

"*§ 35.23 Requirement to calibrate instruments used for full calibration and spot-check measurement.*

"(a)(1) Full calibration measurements required by § 35.21 shall be performed using a dosimetry system that has been calibrated by the National Bureau of Standards (NBS) or by a Regional Calibration Laboratory (RCL) accredited by the American Association of Physicists in Medicine (AAPM). The dosimetry system shall have been calibrated within the previous two years and after any servicing that may have affected system calibration. As an alternative, the dosimetry system shall be calibrated every four years; an independent cobalt-60 intercomparison shall be made midway (± 6 months) in the period; and suitable records shall be kept to provide constancy of the dosimetry system.

"(2) Independent cobalt-60 intercomparisons shall be sponsored by a professional organization; such as a chapter of the AAPM, the Radiological Physics Center (RPC), or a regional Center for Radiological Physics (CRP). Such intercomparisons shall *not* provide a calibration factor for the dosimetry system but will provide a check to determine that the existing calibration factor is valid. If such a dosimetry system intercomparison demonstrates that the calibration factor appears to have changed by more than 2%, then the dosimetry system shall be recalibrated at the NBS or an RCL.

"(3) Consistence of dosimetry system performance shall be verified before and after calibration by the NBS or an RCL, before and after a dosimetry system intercomparison, and at least quarterly thereafter, or prior to the use of a dosimetry system if the interval is greater. A cobalt-60 teletherapy source, with a jig for positive positioning of the ionization chamber, or a shielded Strontium-90 or other long-lived radioactive source, may be used for such constancy checks.[1] The time of irradiation shall be long compared to the time required to start and stop an irradiation. Corrections shall be made for radioactive source decay, and ambient temperature and pressure; attention shall be paid to possible errors in source or chamber positioning, collimator geometry, and timers. For field instruments changes or fluctuations of ± 1% are normal."

* * * * *

"*§ 35.25 Records.*

* * * * *

"(a) Records of (1) full calibration measurements under § 35.21 and (2) dosimetry system intercomparisons using Co-60, and (3) constancy checks of the dosimetry system used to make these measurements under § 35.23, shall be preserved for at least five years after completion of the full calibration."

* * * * *

The petitioner presents the following rationale for these suggested amendments.

"The AAPM considers it essential to maintain high standards of calibration for dosimetry systems used in the calibration of teletherapy units. Since the capacity of the NBS and RCLs is limited, an alternative method has been suggested to maintain these high standards while reducing the load on the calibration laboratories. Members of the AAPM are almost invariably the physicists responsible for the calibration of teletherapy units.

"The specific issues involved are the need to insure high accuracy in the calibration of teletherapy units and, within the capabilities of the calibration laboratories, to assure that dosimetry systems provide this accuracy. The recommendations made above are to change the requirement for dosimetry system calibrations every two years by the NBS or an RCL, to an alternative of requiring a calibration every four years with a dosimetry system intercomparison midway in the period and constancy checks throughout the four year period. The current rule could result in the use of a defective dosimetry system for a period as long as two years if, for example, it was damaged in transit or an error was made in the calibration. It is difficult, on short notice, to collect data showing that instrument calibrations stay constant over periods of many years. A number of qualified physicists who calibrate instruments and machines, believe that an initial calibration with proper constancy checks and dosimetry system intercomparisons would provide a better way to assure proper dosimetry system accuracy, than a new calibration every two years. Rationale for a longer period between calibrations was included in the IAEA 'Manual of Dosimetry in Radiotherapy' in 1970. A recent publication by Karzmark (1980) reported on constancy checks and intercomparisons for periods up to 14 years. For integrated dose data, the average standard deviation for six field instruments was 0.79%. Shalek et al (1981) reported on intercomparisons and calibrations with several different dosimetry systems. The results presented indicated that reliability of the dosimetry system or chamber calibration factor proved by the NBS or an RCL was unrelated to the number of years since calibration. The current rule is unduly burdensome because the calibration facilities of the NBS and RCLs are limited and at present there is a backlog of about six months."

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[1] A compact constancy checker shall *not* be used for dosimetry system intercomparisons.

The petitioner cites the following references.

"Massey, John B., IAEA Technical Report No. 110, "Manual of Dosimetry in Radiotherapy", p. 26, 1970.

Karzmark, C. J., "Concerning radiotherapy standard dose meter calibration" Med. Phys. 7, 574–5, 1980.

Shalek, R. J., Humphries, L. J. and Hanson, W. F., "The American Association of Physicists in Medicine Regional Calibration Laboratory System", Proceedings of a Meeting on Traceability for Ionizing Radiation Measurements, NBS Special Publication 609, in press, 1981."

The petitioner requested that the suggested amendments be handled in accordance with the expedited procedure for handling certain petitions for rulemaking set out in 10 CFR 2.802(e). (46 FR 35486, July 9, 1981). Although NRC is announcing the receipt of the petition and requesting public comment on it in accordance with the standard procedures set out in 10 CFR 2.802(e), NRC intends to respond promptly to the petition. The NRC is currently developing a proposed revision to Part 35 in its entirety for publication in Spring, 1982. The NRC intends to investigate possible alternatives to the petitioner's suggested solution to the problem and analyze public comment received in response to this notice of petition for rulemaking. If the NRC then determines that an amendment is necessary, the proposed change will be included in the proposed revision of Part 35. Meanwhile, any licensee who anticipates difficulty in having instruments calibrated within the required two year period may request a specific exemption from this requirement under the provision of 10 CFR 30.11(a).

A request for an exemption should be addressed to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

Dated at Washington, DC, this 25th day of January 1982.

For the Nuclear Regulatory Commission.

John C. Hoyle,

Acting Secretary of the Commission.

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49 FR 8621
Published 3/8/84

10 CFR Part 35

[Docket No. PRM-35-5]

Nuclear Radiation Consultants: Receipt of a Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking.

SUMMARY: The Nuclear Regulatory Commission is publishing for public comment a notice of receipt of a petition for rulemaking submitted by Nuclear Radiation Consultants. The petition requests that the NRC amend its regulations governing the human uses of byproduct material to permit any health professional with appropriate training and experience to obtain a license authorizing the use of a specific medical diagnostic device containing a radiation source. The petitioner requests this action so that a greater number of health professionals could be licensed to use the device.

DATE: Submit comments by May 7, 1984. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

ADDRESSES: Submit comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Attention: Correspondence and Records Branch.

Hand deliver comments to: Room 1121, 1717 H Street NW., Washington, D.C. between 8:15 a.m. and 5:00 p.m.

For a copy of the petition write: Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

Inspect and copy comments received on the petition at: The NRC Public Document Room, 1717 H Street NW., Washington, D.C.

FOR FURTHER INFORMATION CONTACT: John Philips, Chief, Rules and Procedures Branch, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Telephone: (301) 492–7086 or Toll Free (800) 368–5642.

SUPPLEMENTARY INFORMATION: The Nuclear Regulatory Commission has received a petition for rulemaking from Nuclear Radiation Consultants. This petition for rulemaking has been assigned Docket No. PRM-35-5.

The petitioner requests that the NRC amend its regulations governing the human uses of byproduct material to permit any health professional with appropriate training and experience to obtain a license to use a specific medical diagnostic device that contains a radioactive source. This device is a dual photon spine scanner, also known as a bone mineral analyzer, that uses the radioactive isotope 153 Gd. The device is useful in diagnosing osteoporosis, a disorder common in women over 60 years old.

Currently, NRC regulations require that persons authorized to use sources and devices containing byproduct material be physicians, as defined in 10 CFR 35.3(b), who meet specified training and experience requirements. In Policy and Guidance Directive FC 83–24, the NRC determined that dentists and podiatrists could be exempted from the requirement that the person authorized to use radioactive material be a physician if the proposed dentist or podiatrist user—

1. Is licensed to practice dentistry or podiatry by a State or territory of the United States, District of Columbia, or Commonwealth of Puerto Rico; and
2. As a minimum, has received a total of eight hours of training in basic radiation physics and instrumentation, radiation biology, and radiation protection.

The petitioner's requested amendment would allow any health professional with the training and experience required by FC 83–24 to become licensed to use 153 Gd in bone mineral analyzers. The petitioner believes that NRC's requirements are unduly restrictive because individuals who have the training and experience required by FC 83–24 but are not physicians are not able to become authorized users. The petitioner contends that the use of the device cannot be considered the practice of medicine because it is a diagnostic tool used to acquire information. Therefore, the petitioner considers it unreasonable to believe that only physicians are capable of using bone mineral analyzers without risk to public health and safety.

The NRC invites public comment on PRM-35-5. Those who intend to submit comments on the petition may obtain a copy of the petition from the Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

Dated at Washington, D.C., this 2nd day of March 1984.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

≫ 50 FR 8136
Published 2/28/85

10 CFR Part 35

[Docket No. PRM-35-5]

Nuclear Radiation Consultants; Denial of Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Denial of petition for rulemaking.

SUMMARY: The Nuclear Regulatory Commission is denying a petition for rulemaking submitted by Nuclear Radiation Consultants. The petition requested that NRC regulations be amended to permit any health professional to obtain a license to use the dual photon spine scanner, also known as a bone mineral analyzer, which utilizes radioactive gadolinium-153. Current NRC regulations require that a person must be a physician in order to obtain a license for human use of sources and devices containing byproduct material.

FOR FURTHER INFORMATION CONTACT: Judith Foulke, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone (301) 427–4563.

SUPPLEMENTARY INFORMATION: The Nuclear Regulatory Commission is denying a petition for rulemaking dated January 19, 1984, submitted by Nuclear Radiation Consultants. A notice of filing of the petition was published in the **Federal Register** on March 8, 1984 (49 FR 8621), and public comment was invited.

Twenty-seven comment letters were received and all of the commenters opposed adoption of the petition. Copies of the petition and public comments are available for inspection and may be copied for a fee at the NRC Public Document Room, 1717 H Street, NW, Washington, DC 20555.

Background

The petitioner, Nuclear Radiation Consultants, requested the NRC to amend its regulations governing the human use of byproduct material to permit any health professional with appropriate training and experience to obtain a license to use a specific medical diagnostic device containing the radioactive isotope Gd-153. This device is the dual photon spine scanner, which is also known as a bone mineral analyzer. By measuring the transmission of radiation through the spinal bones, the condition of the skeleton can be assessed.

As described in the Commission's February 9, 1979 policy statement, "Regulation of the Medical Uses of Radioisotopes" (44 FR 8242):

> The NRC and its predecessor the Atomic Energy Commission have regulated the medical uses of radioisotopes since 1946. AEC recognized that physicians have the primary responsibility for the protection of their patients and designed its regulations accordingly. The physicians were required to be licensed by the State, and their applicable training and experience were evaluated in consultation with the Advisory Committee on the Medical Use of Isotopes.

An NRC license for the medical use of radioisotopes is not a license to practice medicine. It has a different purpose, namely, assuring the safe handling and use of radioisotopes. To the extent that it affects the practice of medicine, it does so no more than necessary to protect public health and safety. However, under the Commission's regulations in 10 CFR Part 35, a physician must be licensed by a State to practice medicine prior to receiving an NRC license. NRC's license involving irradiation of humans is restricted to State-licensed physicians because of the need for the requisite competence to practice medicine that is demonstrated by a license from a State.

As is the case with X-ray machines and other diagnostic equipment, the actual measurements may be made on the patient by paramedical personnel. These technicians and technologists are trained in the use of the specific devices by their physician-supervisor in addition to their formal schooling and are supervised by the physician who is responsible for care of the patients. NRC has recognized this situation from the beginning and discusses the permissible scope of activities for a technician in section 4 of Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Programs."

NRC has provided an exemption from its requirements that only physicians can obtain a license for human use of byproduct material by allowing podiatrists and dentists to be licensed to use the lixiscope, a device similar to an X-ray machine. The rationale for this exemption was based on the fact that these professionals must also be licensed by a State to treat specific portions of the human body.

Issues Raised by Commenters

Among the concerns expressed by the commenters was the potential for erroneous interpretation of the results. These commenters pointed out that complications due to coexistent osteoarthritic or post-surgical changes in the spine may lead to failure to diagnose the serious medical condition of osteoporosis or to initiation of therapy with possibly harmful agents such as estrogens for patients not in need of it. As is true for all areas of clinical medicine, diagnostic results must be interpreted only by individuals who understand the primary and coexistent medical problems of the patient. In addition, allowing non-physicians to be licensed to use the bone mineral analyzer could lead to unnecessary radiation exposure since tests would be more likely to be performed on individuals not needing them. This would be contrary to the Commission's policy that all radiation exposures should be balanced by a concomitant benefit.

Commenters also noted that, while under optimal conditions the doses to the patient and the operator resulting from the use of a bone mineral analyzers are acceptably small, situations can arise which present significant radiation safety hazards. Improper positioning of the patient or failure of the device to move as programmed can result in overexposure of the patient. Instances were cited where the gadolinium source was found to contain another radionuclide, which produced a much higher dose rate, or was leaking, which produced transferable contamination. While these occurrences are rare, they do demonstrate that the bone mineral analyzer is not as innocuous as the petitioner claimed.

NRC Responses to Issues Raised in Petition

Issue 1: The petitioner claims "The use of this device cannot reasonably be considered the practice of medicine because it is solely a diagnostic tool."

Response 1: As pointed out in several comment letters received from professional medical societies, diagnosing disease has always been an integral part of the practice of medicine. Consequently, use of diagnostic tools on humans definitely falls within the definition of the practice of medicine.

Issue 2: The petitioner claims "It is unreasonable to believe only physicians are capable of using bone mineral analyzers without risk to public health and safety. NRC is aware that nuclear medicine technologists with one year training past secondary school routinely administer intravenously substantial doses of radiopharmaceuticals. NRC is aware these materials deliver far greater radiation doses than the 10–20 mrem dose to a limited anatomical area resulting from use of the bone analyzer."

Response 2: We agree that other individuals such as medical technologists can operate this device safely. However, NRC does not license technologists because responsibility for patient care is vested in a named individual licensed to practice medicine by a State. In this regard, the magnitude of the radiation dose is not the issue of concern. As noted above, the delegation of operation of devices to paramedical personnel with the proper training and under the supervision of a licensed physician is acceptable.

Issue 3: The petitioner claims ". . . there are individuals trained in radiation physics and health physics who are often the very instructors in the subjects required by NRC in the directive noted above."

Response 3: We agree that there are other individuals who meet the training criteria as far as radiation physics and health physics are concerned. However, these individuals are not licensed by a State to practice medicine.

Issue 4: The petitioner claims that NRC's licensing policy is "de facto antitrust in that it blocks entry of individuals with pertinent and equal training and experience from becoming licensed users."

Response 4: We assume from the latter part of the sentence that the petitioner meant to say that NRC was contributing to establishment of a monopoly (not "antitrust"). If this were the case, it would be an indirect consequence of NRC's carrying out its charter from Congress to protect the public health and safety.

Issue 5: The petitioner claims that NRC's licensing policy for the human use of byproduct materials is contrary to the Regulatory Flexibility Act.

Response 5: NRC Policy Directive FC-83-24, "Licensing the Lixiscope and Bone Mineral Analyzer for Human Use," contary to what the petitioner asserts, is not in conflict with the intent of Congress as spelled out in the Regulatory Flexibility Act. First of all, the Regulatory Flexibility Act, 5 U.S.C. 601–612, is only applicable to agency rulemakings on which public comment is required by section 533(b) of the Administrative Procedure Act or any other law. Second, the Regulatory Flexibility Act establishes a *procedure* for evaluating the effect of agency regulations on small entities. All agencies, as part of the rulemaking process, must prepare a regulatory flexibility analysis for any rule that has a significant economic impact on a substantial number of small entities. The analysis must, among other things, discuss how a rule will affect small entities, describe significant alternatives that would minimize any significant economic impact of the rule on small entities, and explain why each one of such alternatives was rejected. The intent of the Act is to require government agencies to review proposed rules to ensure that, while accomplishing their intended purpose, they do not unduly affect the ability of small entities to carry out their activities. Contrary to the implications of the petitioner's letter, the Act does not require the agency to make the accommodation of any and all small business interests its paramount concern at the expense of the agency's other satutory resonsibilities. To the countrary, Section 606 of the Regulatory Flexibility Act states that the requirement to analyze the economic impact of agency regulations to determine their impact upon small entities does not alter in any manner the standards otherwise applicable by law to agency action.

Issue 6: The petitioner claims that NRC's policy is ". . . inconsistent with the mandate of NRC to encourage safe uses of radioactivity."

Response 6: NRC's mandate is to assure the safety of workers and the public. NRC has never had any mandate to encourage the use of radioactive materials. In fact, one of the reasons why the Atomic Energy Commission was divided into two agencies (NRC and ERDA, now DOE) was to separate the regulatory and promotional activities that related to the use of radioactive materials.

Conclusion

A bone mineral analyzer is used only as a means of obtaining information on a patient's skeletal status in order to diagnose diseases such as osteoporosis. Diagnosing diseases has always been construed by all levels of government as an integral part of the practice of medicine. Consequently, NRC has always issued licenses involving human use of byproduct material only to licensed physicians (or to podiatrists or dentists for limited use of the Lixiscope) because only they are authorized to practice medicine and possess the demonstrated competence to practice medicine, as evidenced by their State license. The petitioner's statements do not provide adequate justification for changing this policy.

Dated at Bethesda, Maryland, this 1st day of February, 1985.

For the Nuclear Regulatory Commission.

William J. Dircks,

Executive Director for Operations.

UNITED STATES NUCLEAR REGULATORY COMMISSION
RULES and REGULATIONS
TITLE 10, CHAPTER 1, CODE OF FEDERAL REGULATIONS—ENERGY

PART 35

HUMAN USES OF BYPRODUCT MATERIAL

STATEMENTS OF CONSIDERATION

30 FR 8185
Published 6/26/65
Effective 8/25/65

See Part 30 Statements of Consideration.

32 FR 14265
Published 10/14/67
Effective 11/13/67

Licenses for Groups of Diagnostic Uses

On November 5, 1966, the Commission published in the FEDERAL REGISTER (31 F.R. 14317) proposed amendments of 10 CFR Part 35, "Human Uses of Byproduct Material". A new § 35.100 defined two groups of diagnostic uses of radioisotopes with well-established clinical procedures and a new § 35.14 set forth the licensing requirements for each group and specified that an application for a license for any diagnostic use within a group would be considered by the Commission as an application for all of the uses within the group if the applicant satisfied the licensing requirements for the group.

All interested persons were invited to submit written comments and suggestions for consideration in regard to the proposed amendments within 60 days after publication in the FEDERAL REGISTER.

The commments received in response to the proposed amendments suggested that additional diagnostic uses of byproduct material be included. Upon consideration of the comments and other factors involved, the Commission has concluded that the proposed amendments, with the addition of four well-established diagnostic uses of byproduct material to the schedule in § 35.100, should be published as an effective rule. The text of the new § 35.100, set out below is identical to the text of the proposed § 35.100 published on November 5, 1966, except for the addition of iron 59 as sulfate for iron turnover studies, iodine 131 as sodium iothalamate for kidney function studies, and potassium 42 as chloride for potassium space determinations to Group I and the addition of mercury 203 as chlormerodrin for brain scans to Group II. It should be noted that mercury 203 for kidney scans has not been included in Group II.

The text of the new § 35.14 has been slightly rephrased to clarify that an application for any one or more uses in a group will be approved for all of the uses in the group if the licensing requirements for the group have been satisfied.

Pursuant to the Atomic Energy Act of 1954, as amended, and the Administrative Procedure Act of 1946, as amended, the following amendments of 10 CFR Part 35 of the Commission's regulations are published as a document subject to codification, to be effective thirty (30) days after publication in the FEDERAL REGISTER.

35 FR 6425
Published 4/22/70
Effective 5/22/70

See Part 30 Statements of Consideration.

39 FR 26143
Published 7/17/74
Effective 8/16/74 (Parts 31 & 32)
Effective 1/13/75 (Part 35)

Group Licensing for Certain Medical Uses

The Atomic Energy Commission published in the FEDERAL REGISTER on January 21, 1974 (39 FR 2384) proposed amendments to its regulations in 10 CFR Parts 31, 32, and 35 to add certain materials and uses to Groups I and II of medical uses of byproduct material, to establish several new groups of medical uses, to specify licensing requirements for the distribution of byproduct material to group licensees, and to add new byproduct material to the general license for certain in vitro clinical and laboratory testing.

Interested persons were invited to submit written comments or suggestions for consideration in connection with the proposed amendments within 45 days after publication of the notice of proposed rule making in the FEDERAL REGISTER.

After consideration of the comments received and other factors involved, the Commission has adopted the proposed amendments to 10 CFR Parts 31, 32, and 35, with certain modifications.

Some modifications in the regulations, based on discussions with the Food and Drug Administration (FDA), have been made in order to provide an orderly transition of the regulation of pharmaceutical safety and effectiveness of radiopharmaceuticals from the Commission to the FDA, and to prevent any disruption in the existing supply and distribution of these drugs.

Licenses issued by the Commission that are in effect on the effective date of these amendments and that specifically authorize investigational use of byproduct material will continue in effect according to their terms and until their expiration dates. Specific licenses of broad scope that are in effect on the effective date of these amendments and that authorize the use of byproduct material for medical research, diagnosis, and therapy without listing specific materials or uses will continue in effect according to their terms and until their expiration dates. The authority granted in these licenses by the AEC does not, however, exempt the licensee from any FDA regulations. After the effective date of the amendments, the Commission will continue to issue specific licenses for materials and uses which are not included in the group licenses pursuant to §§ 35.14 and 35.100. Some well-established diagnostic and therapeutic uses are omitted from the groups because they involve radiation protection procedures which are not similar to those required for the uses listed in the groups. Some other omitted uses, such as metabolic tracer studies, are not now regulated by FDA as diagnostic or therapeutic radiopharmaceutical uses but FDA has informed the AEC that it intends to promulgate regulations regarding these uses in the near future. Authorization to use new investigational radiopharmaceuticals which are not in the group licenses will be granted upon notification from FDA that it has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) in accordance with previously established administrative procedures until such time as FDA terminates its existing exemption to 21 CFR 312.1 (formerly 21 CFR 130.3) for radiopharmaceuticals and brings the control of safety and efficacy of these drugs fully under its regulations.

PART 35 • STATEMENTS OF CONSIDERATION

When the amendments to 10 CFR Part 35 become effective, byproduct material for use under group licenses must have been manufactured, labeled, packaged, and distributed in accordance with a specific license issued by the Commission pursuant to § 32.72, 32.73, or 32.74 or in accordance with a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations. In order to allow manufacturers of such products to be licensed prior to the effective date of requirements for licensees to obtain materials from such licensed manufacturers, and to ensure the availability of licensed products for group licensees, §§ 32.72, 32.73, and 32.74 will become effective 150 days before the amendments to §§ 35.14 and 35.100 become effective. In the meantime, licenses that authorize the present Groups I and II and licenses that authorize specified materials and uses will remain in effect. Further, §§ 32.72, 32.73, and 32.74 have been changed from the proposed rule to provide that any manufacturer who makes application within 60 days of the effective date of §§ 32.72, 32.73, and 32.74 to distribute to group licensees a product that was distributed commercially to licensees of the Commission on or before the effective date of §§ 32.72, 32.73, and 32.74 may continue distribution of such product to group licensees until the Commission issues the license pursuant to § 32.72, 32.73 or 32.74 or notifies the applicant manufacturer otherwise.

Sections 32.72 and 32.73 have been changed to provide that a manufacturer who applies for a license to distribute radiopharmaceuticals, or generators and reagent kits for the preparation of radiopharmaceuticals shall submit evidence that such product will be manufactured, labeled and packaged in accordance with the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act or that the manufacture and distribution of such product are not subject to those Acts. This will provide more flexibility in how compliance with appropriate Food and Drug Administration requirements can be established as a requirement for issuance by the Commission of a license to distribute radiopharmaceutical products to group licensees.

The present title of 10 CFR Part 32 is "Specific Licenses to Manufacture, Distribute, or Import Exempted and Generally Licensed Items Containing Byproduct Material". Since the new §§ 32.72, 32.73 and 32.74 apply to licensing the manufacturer of radiopharmaceuticals, sources and devices containing byproduct materials for distribution to group specific licensees, the title of 10 CFR Part 32 is changed to "Specific Licenses to Manufacture, Distribute or Import Certain Items Containing Byproduct Material".

The following changes in the effective rule from the proposed rule are based primarily on the public comments received.

(1) Section 35.14(a)(3) has been modified to delete the enumeration of specific classes of persons, other than physicians, who participate in the use of radioactive materials, since classes of persons in addition to those enumerated can be involved in the human use of radioactive materials.

(2) Section 35.14(b) (4) and (5), which would have required persons using investigational radiopharmaceuticals to register with the Commission have been deleted because such registration would be an unnecessary duplication of regulatory effort by the Commission and the FDA. The subsequent paragraphs of § 35.14(b) have been renumbered accordingly. Conforming changes have been made in § 35.100 to delete references to § 35.14(b)(4) concerning such registration.

(3) Paragraph 35.14(b)(7), which would have required hospitalization of patients containing more than 8 millicuries of iodine 131 for the treatment of thyroid carcinoma or more than 23 millicuries of gold 198, has been deleted. These values are the most conservative ones recommended by the National Council on Radiation Protection and Measurements in NCRP Report No. 37, and were not intended for use in all situations.

Requirements for hospitalization of such patients will continue in accordance with current licensing practices, pending consideration of modifications to such requirements in future rule changes.

(4) Section 35.14(b)(8)(i), renumbered § 35.14(b)(5)(i), has been changed to provide that required leak tests on sources and devices may be permitted at intervals longer than six months, as is now provided for certain industrial sources, when sufficient information is furnished by the manufacturer to demonstrate that such longer interval is justified by performance characteristics of the source or device and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source or device. Provisions for approval of leak test intervals longer than six months have been added to § 32.74.

(5) Section 35.14(d) has been changed to provide additional flexibility in the use of byproduct material for calibration and reference standards by providing larger sources of certain standards which are needed and used in nuclear medicine and by establishing more specific manufacturing and use standards for such larger sources.

(6) Xenon 133 has been deleted from § 35.100 (a) Group I and (b) Group II because the use and disposal of xenon 133 requires specialized equipment and procedures for occupational and public health and safety that are not required for other byproduct materials in these groups. This radioisotope will continue to be specifically licensed for blood flow, pulmonary function and heart and lung imaging studies.

(7) Iodine 131 as IHSA for cisternography has been deleted from § 35.100(b) Group II because this product in high specific activity form suitable for cisternography has not been made commercially available or licensed by FDA for this purpose. I-131 as low specific activity IHSA, which is licensed by FDA and distributed for other uses, is not appropriate for use in cisternography because the use of low specific activity IHSA for cisternography can cause adverse reactions in patients. This use will be reconsidered when a suitable product is commercially available.

(8) The use of gold 198 and phosphorus 32 colloids for interstitial use have been deleted from § 35.100(d) Group IV because the training, experience and procedures requirements for these seldom used procedures are different from such requirements for other materials and uses in the group. These radiopharmaceuticals will continue to be specifically licensed for interstitial therapy.

(9) Technetium 99m as pertechnetate for blood flow studies and mercury 197 as chlormerodrin for kidney function studies have been added to § 35.100(a) Group I, iodine 125 as sodium iodide for thyroid imaging has been added to § 35.100(b) Group II, and technetium 99m as pertechnetate for use with reagent kits for preparation of radiopharmaceuticals containing technetium 99m has been added to § 35.100(c) Group III in order to be consistent with current licensing practices for well established procedures. Subsequent listings in these groups have been renumbered accordingly.

(10) Section 35.100(d) Group IV has been divided into § 35.100(d) Group IV for therapeutic uses that do not usually require facilities and procedures for hospitalization of patients for purposes of radiation safety and § 35.100(e) Group V for therapeutic uses that require facilities and procedures for hospitalization of patients for radiation safety. Proposed § 35.100(e) Group V for sources and devices has been renumbered § 35.100(f) Group VI. Conforming paragraph number changes have been made in the cross references in § 35.14 (b).

(11) Editorial and clarifying changes have been made.

A number of commentators suggested that cobalt 57 be added to § 35.14(d) as calibration and reference standards, to § 35.100(a) Group I as cyanocobalamin, and to §§ 31.11 and 32.71 for in vitro use. While cobalt 57 is a widely used isotope in nuclear medicine, it is not byproduct material as defined in the Atomic Energy Act (i.e., it is not produced in a nuclear reactor) and it is therefore not subject to regulation by the Commission.

Two commentators suggested that I-125 as interstitial seeds be added to § 35.100(e) Group V, now renumbered § 35.100(f) Group VI. This isotope and use is still undergoing clinical evaluation and it is not yet considered a well-established use for listing in the group.

Section 35.14 provides that an application for a license for any use of byproduct material in one of the groups will be approved for all of the uses in that group if the applicant's experience, training, equipment and procedures are adequate for all uses in that group. In some cases, the applicant's qualifications may be appropriate for certain specified materials and uses but not for all of the uses in a group, in which cases the license may be issued only for specified materials and uses.

If a person who already holds a specific license for specified medical uses of byproduct material applies for a license amendment to add any use in § 35.100, the Commission will consider amendment of the license for all the groups of uses in § 35.100 which include the uses previously licensed.

Pursuant to the Atomic Energy Act of 1954, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to 10 CFR Parts 31, 32, and 35 are published as a document subject to codification.

40 FR 8774
Published 3/3/75
Effective 3/3/75

Energy Reorganization Act; Revisions to Chapter 1 to Reflect Organizational and Procedural Changes

See Part 2 Statements of Consideration.

40 FR 26679
Published 6/25/75
Effective 6/25/75

PART 35—HUMAN USES OF BYPRODUCT MATERIAL

Group Licensing for Certain Medical Uses

Notice is hereby given of the amendment of the Nuclear Regulatory Commission's regulation "Human Uses of Byproduct Material," 10 CFR Part 35.

Section 35.100 of 10 CFR Part 35 lists groups of medical uses of radioisotopes that have similar requirements for user training and experience, facilities and equipment, and radiation safety procedures.

The notice of proposed rulemaking that was published in the FEDERAL REGISTER on January 21, 1974 (39 FR 2384) stated that the groups of licensed uses would be amended from time to time to add new radiopharmaceuticals, sources, devices, and uses as they are developed. The use of iodine 125 as seeds for interstitial treatment of cancer has become a well-established clinical procedure and is hereby added to Group VI. An editorial correction is also made in § 35.100(d)(1) to correct the spelling of "hyperthyroidism."

Because these amendments relate solely to procedural matters, the Commission has found that good cause exists for omitting notice of proposed rulemaking, and public procedure thereon, as unnecessary. Since the amendments relieve licensees from restrictions under regulations currently in effect, they may become effective without the customary 30-day notice.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, and sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 35 are published as a document subject to codification.

41 FR 16445
Published 4/19/76
Effective 4/19/76

Miscellaneous Changes to Chapter

See Part 20 Statements of Consideration.

41 FR 16448
Published 4/19/76
Effective 4/19/76

PART 35—HUMAN USES OF BYPRODUCT MATERIAL

Group Licensing for Certain Medical Uses

Notice is hereby given of the amendment of the Nuclear Regulatory Commission's Regulation "Human Uses of Byproduct Material," 10 CFR Part 35.

Section 35.100 of 10 CFR Part 35 lists groups of medical uses of radioisotopes that have similar requirements for user training and experience, facilities and equipment, and radiation safety procedures.

The notice of proposed rulemaking that was published in the FEDERAL REGISTER on January 21, 1974, (39 FR 2384) stated that the groups of licensed uses would be amended from time to time to add new radiopharmaceuticals, sources, devices, and uses as they are developed. The Food and Drug Administration (FDA) has approved a "New Drug Application" for ytterbium 169 as labeled diethylenetriaminepentaacetic acid (DTPA) for cisternography and this procedure is hereby added to Group II.

Because this amendment relates solely to procedural matters, the Commission has found that good cause exists for omitting notice of proposed rulemaking, and public procedure thereon, as unnecessary. Since the amendment relieves licensees from restrictions under regulations currently in effect, they may become effective without the customary 30-day notice.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and Sections 552 and 553 of Title 5 of the United States Code, the following amendment to Title 10, Chapter I, Code of Federal Regulations, Part 35 is published as a document subject to codification.

42 FR 25721
Published 5/19/77
Effective 5/19/77

GAO Clearances; Reporting and Record Keeping Requirements

See Part 20 Statements of Consideration.

42 FR 28891
Published 6/6/77
Effective 7/6/77; §§21.6, 21.21(a), and 21.51 effective 1/6/78
(7/6/77 effective date extended to 8/10/77)

Reports to the Commission Concerning Defects and Noncompliance

See Part 21 Statements of Consideration.

42 FR 36240
Published 7/14/77
Effective 8/15/77

PART 35—HUMAN USES OF BYPRODUCT MATERIAL

Specific Licenses to Individual Physicians and Institutions

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule

SUMMARY: The Nuclear Regulatory Commission is amending its regulations to require most medical institutions to be licensed for the use of radioactive material in the institution, rather than the individual physician using the radioactive material. Problems of administering multiple licenses at the same institution created the need for the rule change. The intended effect of the action is to require medical institutions to be responsible for the protection of all staff, patients, and members of the public who may come within range of radiation from its activities.

EFFECTIVE DATE: August 15, 1977.

FOR FURTHER INFORMATION CONTACT:

Edward Podolak, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, phone 301-443-6910.

SUPPLEMENTAL INFORMATION: On March 3, 1977, the Nuclear Regulatory Commission (NRC) published a proposed rule (42 FR 12185) to amend its regulations in § 35.12 to limit the granting of individual physician licenses to a physician or group of physicians in private practice in an office outside of an institution. The effect of this rule change is to require medical institutions, now operating nuclear medicine programs under individual physician licenses, to be licensed as institutions under § 35.11 at the time of expiration of the individual physician licenses obtained under § 35.12.

Under current NRC regulations, the NRC issues licenses for human use of radioactive (byproduct) material (1) to medical institutions, (2) to physicians for practice in offices outside of medical institutions and (3) to some physicians for practice within medical institutions. The current regulations are not clear as to when it is appropriate for a physician practicing at an institution to hold the license and when the institution should hold it. As a consequence, the physician alone holds the license in some cases (260), the hospital in other cases (1450), and both the hospital and the physician in still others (90). Regulatory enforcement problems might arise when both the hospital and the individual physician practicing therein hold a license or when several physicians practicing in a hospital hold individual licenses. For regulatory purposes, if workers or visitors are overexposed to radiation, it may be difficult to pin-point primary responsibility for the improper practices. Is the licensed hospital or the licensed physician responsible? If two physicians hold licenses, is one physician responsible or are both physicians responsible? This failure to establish clear lines of responsibility may result in the omission of necessary safety procedures or the assertion of conflicting procedures—either condition may generate avoidable radiological hazards.

This rule change is based on the concept that when radioactive material is used on the premises of a medical institution, the institution and not the authorized physicians should hold the NRC license. In the NRC institutional license the individual physicians are designated by name as the authorized users of byproduct material in the institution. This rule change will not affect medical institutions (or physicians designated as individual users in medical institutions) that already hold an NRC license. Neither would the proposed change affect physicians who hold NRC licenses for practice in their offices outside of medical institutions.

The rule change will have a minimal effect on physicians who hold individual NRC licenses that currently authorize practice in an institution. In order for such a physician to continue to practice nuclear medicine in a medical institution he will have to be named on the institution's license by the time his individual physician license expires. At the expiration of the individual physician license, the Commission will not renew authorization for practice within a medical institution. Medical institutions that already hold an institution license are encouraged to add the names of individual physicians to their institution license immediately, rather than wait until the physician's individual license expires. The proposed rule change, in effect, provides that institutional licenses and individual physician licenses are mutually exclusive.

Seven of the 15 letters received in response to the proposed rule were favorable. Seven letters objected to the proposed rule in whole or in part and one letter discussed a point that was beyond the scope of the proposed rule but will be considered by the NRC for rule making action in the future.

DISCUSSION OF MAJOR COMMENTS

INDIVIDUAL VS. INSTITUTIONAL RESPONSIBILITY

One commenter stated that greater accountability is provided by individual licensures since the licensee is responsible and must provide adequate safety regulations under existing hospital rules and regulations. He further stated that the accountability is diluted with a committee on safety composed of a number of members meeting at irregular intervals in a monitoring group and continued administration is better provided by individual licensing within the bylaws, rules, and regulations of the hospital.

Under NRC regulations, both for medical institution licenses and individual physician licenses, the day-to-day responsibility for the proper use of radioactive materials rests with the physician supervising the radioisotope procedures. Under an NRC institutional license, the licensee must appoint a medical isotopes committee. The individual physician license does not require appointment of a medical isotopes committee either for practice in a private office or in an institution. Institutional responsibility is as clearly focused under the institution license as the individual physician responsibility under the physician license. The medical isotopes committee assists the physicians and the institutions management in structuring and administering a safe and effective nuclear medicine program. This assistance helps to assure that NRC regulations will be observed but does not transfer ultimate responsibility for compliance with the regulations from the institution to the medical isotopes committee.

MORE COMMENTS ON MEDICAL ISOTOPES COMMITTEE

Two comments were received concerning the effect on smaller- or intermediate-size institutions of requiring a medical isotopes committee under the institutional NRC license. One comment suggested that committees from large institutions could act as the committee for smaller institutions or function as an active consultant to the local committee. The other comment suggested that the medical isotopes committees in small hospitals would function as a committee in name only, thereby jeopardizing the hospital's position in the event an inspection is made.

The Commission is aware of the apparent burden on smaller institutions of the following wording in § 35.11(b) regarding the appointment of a medical isotopes committee: "Membership of the committee should include physicians expert in internal medicine, hemotology, therapeutic radiology, and a person experienced in assay of radioisotopes and protection against ionizing radiations;" (emphasis added). The use of "should" in the regulation connotes a strong recommendation. However, in the case of smaller- or intermediate-size institutions with limited nuclear medicine programs the membership of such a committee might properly be composed of a physician trained in nuclear medicine, a person trained in radiation safety and a representative of the institution's management.

The Commission does not accept the suggestion that medical isotopes committees may function in name only in small hospitals. All NRC institutional licensees are expected to have functioning medical isotopes committees.

The Commission is considering alternatives to the present medical isotopes committee such as a radiation safety committee with a simplified, contemporary membership scheme that would be responsible for coordinating the use of byproduct material and monitoring the institution's radiation safety program. The Commission is not presently inclined to accept the suggested alternative of committees from larger institutions acting for smaller institutions. Although voluntary joint medical isotopes committees have worked well in metropolitan areas, the Commission feels that such a requirement might jeopardize the autonomy of the smaller institutions.

CALIBRATION SOURCES

One commenter suggested that calibration sources be added to the list of permissible uses of byproduct material in § 35.12(b)(1). This comment is helpful. A new § 35.12(b)(2)(iv) has been added to include the calibration and quality control checks of radioactive assay instrumentation, radiation safety instrumentation and diagnostic instrumentation in the list of permissible uses of byproduct material under the exception for individually licensed physicians practicing in small hospitals.

THE EXCEPTION

There were three adverse comments concerning the proposed exception for small hospitals in § 35.12(b) that would allow individually licensed physicians to use byproduct material in institutions not licensed by NRC, provided they bring the radioactive material with them and remove it when they depart. The institution would not be allowed to receive, possess or store byproduct material other than the amount of material remaining in the patient. One commenter asked if the proposed exception included the licensing of mobile nuclear medicine laboratories and suggested that it should not. The same commenter suggested that the exposure to the physician during transport and the increased potential for mishap make the receipt and storage of material on the premises of an institution preferable to transportation by the physician. Another commenter suggested that under the wording of the proposed exception, the physician would be required to take the patient with him when he departs, or at least collect and remove the patient's contaminated excreta, rather than permitting the patient to use the sanitary facilities available in the hospital.

The exception to authorize individually NRC licensed physicians to bring nuclear medicine services to institutions and clinics is intended, where appropriate, to include the services provided by mobile nuclear medicine laboratories.

For license approval § 30.33(a)(2) requires that the applicant's proposed equipment and facilities be adequate to protect health and minimize danger to life and property. The authorization for private practice in an institution will be granted only if the physician demonstrates in his license application that he will take adequate measures to provide both for his own safety and the safety of the public while he is using radioactive materials within the institution and while he is transporting radioactive materials to and from the institution. For transporting radioactive materials these measures will include adequate shielding and provisions to prevent spills such as the use of absorbent material and vials with septum seals for injectables.

The language of the proposed rule does not prohibit the common practice of allowing the patient to excrete radioactive material into the sanitary sewer system of a hospital. Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are exempt from the § 20.303 limitations on discharge of NRC licensed material into a sanitary sewerage system. It is not necessary to change the wording of § 35.12(b)(2) to permit a practice that is not prohibited by the rule.

Under this exception, the NRC will hold the physician responsible for all activities conducted under his license both inside and outside the institution.

* * *

INSTITUTIONAL AUTHORITY

Five commenters objected to the proposal for NRC to license institutions rather than the physicians practicing therein, because this action would be an unwelcomed intrusion of the institutions' management into the practice of medicine. According to one commenter, "The shift of de facto clinical authority from physician and medical staff to institutional administration as proposed * * * is detrimental to progress and service in nuclear medicine. The proposed change will encourage and stimulate institutional chauvinism and inhibit interinstitutional cooperation and sharing of services." In strongly-protesting the rule change, another commenter stated that there is ample justification for retention of the present system in order to allow flexibility and avoid a monopoly of nuclear medicine practice created by the internal politics in small hospitals. Another commenter expressed the belief that clarifying language is necessary to insure that the internal policies of institutions do not necessarily exclude qualified physicians from practicing nuclear medicine. Still another commenter stated, "Requiring of licensing of users under an institution is comparable to licensing physicians under an institution (hospital) to practice medicine instead of providing state licensure. This is an unnecessary encroachment on the practice of medicine." Finally, one commenter stated the concern that a physician licensed in one hospital might be prevented from practicing or consulting in another, perhaps less experienced, hospital.

The NRC license is not a license to practice medicine. The physician must be licensed by the State to practice medicine, prior to receiving an NRC license. The NRS license has quite a different purpose—assuring the safe handling and use of radioisotopes. To the extent that it affects the practice of medicine, it does so no more than is necessary to protect radiological health and safety.

Contrary to the suggestion contained in the comments, the Commission believes that the use of institutional licenses should promote flexibility and institutional cooperation. Under the NRC institution license, the individual physicians practicing nuclear medicine in the institution are named in the license application. The addition of another physician to an institutional license would ordinarily be routine. Morover a standard license condition of the institutional license is that a physician may use radioactive material under the supervision of a physician named in the institution's license. This license condition is primarily intended to permit the training of physicians under an institution license but certainly would cover a visiting physician not named in the institution's license as well. In the absence of an institutional license, a physician seeking to use licensed materials at a new location must apply for an entirely new individual license or an amendment to his existing license; in either case this is likely to require a thorough NRC review of the proposed program, equipment, and facilities at the new location.

In the final analysis, it is important to the Commission from a regulatory standpoint that the institution control and be responsible for who uses licensed material within the institution. The NRC is not and cannot be a guarantor against arbitrary staff practices within a medical institution.

COMMENT BEYOND SCOPE

One commenter suggested that the proposed § 35.12(a)(4) be expanded to include certification by the American Osteopathic Board of Nuclear Medicine or the American Osteopathic College of Radiology with proficiency in Nuclear Medicine, as being satisfactory to complete the NRC training requirements. This suggestion is beyond the scope of the notice of proposed rulemaking. The NRC staff is currently studying the possibility of routinely accepting certification by certain medical boards as satisfactory evidence of adequate training for the human use of byproduct material.

Under the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 35 are published as a document subject to codification.

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43 FR 37421
Published 8/23/78
Effective 11/6/78

PART 35—HUMAN USES OF BYPRODUCT MATERIAL

Application Form for Materials License—Medical

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Final rule.

SUMMARY: NRC is amending its regulations to require use of a new form NRC-313M, "Applications for Materials License—Medical". The new form is easier to fill out than the one it replaces, and, on a trial basis, has resulted in reduced correspondence between NRC and the applicants regarding deficiencies in their applications.

EFFECTIVE DATE: November 6, 1978.

Note.—The Nuclear Regulatory Commission has submitted this rule to the Comptroller General for such review as may be appropriate under the Federal Reports Act, as amended, 44 U.S.C. 3512. The date on which the reporting (recordkeeping) requirement of this rule becomes effective, unless advised to the contrary, accordingly reflects inclusion of the 45-day period which that statute allows for such review (44 U.S.C. 3512(c)(2)).

FOR FURTHER INFORMATION CONTACT:

Edward Podolak, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, phone 301-443-5946

SUPPLEMENTARY INFORMATION: Presently, applications for the medical use of byproduct material are filed on the general application form AEC-313 with the aid of a medical licensing guide (NUREG-0338, Rev. 1) which requests information necessary for and specific to the medical application. Form AEC-313 does not have enough space and does not specifically address much of the information requested in the medical licensing guide. A new form NRC-313M has been developed specifically for the medical application. Form NRC-313M does not change the substantive requirements that must be met by applicants for medical licenses. The information required on the new form is the same as that currently identified in the medical licensing guide. However, because the new form NRC-313M is tailored to the medical licensing guide, it is easier for the licensee to use and, on a trial basis, has resulted in less correspondence between NRC and the applicants regarding deficiencies in their applications.

Form NRC-313M and the medical licensing guide are available from the Radioisotopes Licensing Branch, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

Because this notice relates to matters of agency management and procedure, general notice of proposed rulemaking and public procedure thereon are unnecessary and the amendment can be effective 75 days after publication.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 35 are published as a document subject to codification.

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43 FR 55346
Published 11/28/78
Effective 12/28/78

PART 35—HUMAN USES OF BYPRODUCT MATERIAL

Radiation Surveys of Therapy Patients

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Final rule.

SUMMARY: Certain NRC licensees are authorized to treat patients with temporary implants incorporating radioactive material. NRC will require such licensees to confirm the removal of the implants at the end of the treatment by (1) a source count and (2) a radiation survey of the patient. Failure to account for all implants at the conclusion of patient treatment has resulted in some instances of unnecessary radiation exposure to pa-

tients and members of the general public.

EFFECTIVE DATE: The amendment becomes effective on December 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Edward Podolak, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (Phone: 301-443-5966).

SUPPLEMENTARY INFORMATION: NRC regulations in § 35.14(b)(5)(vii) require Group VI licensees [1] to assure that patients treated with cobalt-60, cesium-137 or iridium-192 temporary implants remain hospitalized until the implants have been removed. The primary method for confirming that all sources have been removed is to count the sources implanted and count the sources removed. The source counting has not always been performed accurately, or on a timely basis.

Some patients have been discharged from the hospital with radioactive sources still implanted. (It is particularly difficult to count iridium-192 seeds, which sometimes become dislodged from their encasement in nylon ribbon). Because a backup radiation survey of the patient could have prevented these incidents, on June 28, 1978 NRC published a proposed rule in the Federal Register adding a requirement for source counting and patient radiation surveys to the existing § 35.14(b)(5)(vii) which prohibits Group VI licensees from discharging patients until all sources are removed. The comment period ended August 14, 1978.

Twenty-one comments were received. Eleven favored the proposal without qualification. Three commenters suggested that bulky afterloaded devices that protrude from the body be exempted from the radiation survey. One commenter suggested that an x-ray be permitted as an alternative to the radiation survey. One commenter asked what was meant by "the end of the treatment" and one commenter, while favoring the proposal, suggested that the radiation survey should be performed within one hour of source removal. Four commenters objected to the proposal because they believe that regulations that define what is already good medical practice are useless. One commenter objected to the proposal because he believes that there are some cases where it would be impossible to survey the patient before discharge.

The wording of the final rule is the same as the proposed and requires a radiation survey of the patient before discharge. The radiation survey is the most positive (active) method of verifying source removal. The x-ray is a passive method. Although good practice would suggest a radiation survey soon after source removal, the regulation has to recognize the realities of the clinical setting where other tasks may have higher priority. Placing a tight time limit on this essentially quality control function may interfere with patient care. However, it is extremely unlikely that the licensee will experience difficulty performing the survey between source removal and discharge of the patient.

The suggestion to exempt afterloaded devices is well made. The devices are bulky relative to the actual source size and it is difficult to imagine that patients would be discharged with these devices in-place. However, NRC inspectors, who are familiar with incidents of overexposure from implants remaining in patients, say that this is an area where the "impossible" happens in spite of great care and precautions. Also, NRC inspectors have investigated an incident where a patient was discharged with an afterloaded device in-place with the sources loaded. The radiation survey is simple and inexpensive and it will also detect any sources lost in the bedclothes or room where the survey is performed. Therefore, the afterloaded devices will not be exempted from the requirements for a radiation survey.

Finally, regulations that define what is generally considered good practice may seem useless or may even dismay conscientious licensees. However, this is insufficient reason to forgo these regulations when there is evidence that the good practices are not universal.

Under the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended and sections 552 and 553 of title 5 of the United States Code, notice is hereby given that the following amendment to 10 CFR Part 35 is published as a document subject to codification.

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[1] The most common types of NRC specific licenses for the medical use of byproduct material are the *Group* medical licenses under § 35.14 that apply to those radioactive materials listed in § 35.100. The radioactive materials listed in § 35.100 are divided into six groups, each group having similar requirements for user training and experience, facilities and equipment, and radiation safety procedures. Groups I, II, and III are lists of radiopharmaceuticals for diagnostic procedures; Groups IV and V are lists of radiopharmaceuticals for therapeutic procedures; and Group VI is a list of radioactive medical devices for both diagnostic and therapeutic procedures.

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44 FR 1722
Published 1/8/79
Effective 7/9/79

PART 35—HUMAN USES OF BYPRODUCT MATERIAL

Calibration of Teletherapy Units

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to require medical licensees to (1) calibrate each teletherapy unit annually and (2) perform monthly spot checks on those calibrations. The annual full calibrations must be performed by a qualified expert. The monthly spot checks need not be performed by a qualified expert but the results of the spot checks must be reviewed by a qualified expert on a timely basis.

The amendments will help ensure that a patient receives the prescribed radiation dose by requiring that teletherapy units are properly calibrated.

EFFECTIVE DATE: The amendments become effective on July 9, 1979. Any full calibrations performed in accordance with the procedures in this amendment during the 365 days prior to the effective date of this amendment will count as the first full calibration.

Note—The Nuclear Regulatory Commission has submitted this rule to the Comptroller General for review under the Federal Reports Act, as amended, 44 U.S.C. 3512. The date on which the rule becomes effective, unless advised to the contrary, accordingly reflects inclusion of the 45-day period which that statute allows for this review (44 U.S.C. 3512(c)(2)).

FOR FURTHER INFORMATION CONTACT:

Mrs. Patricia C. Vacca, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (301-427-4232).

SUPPLEMENTARY INFORMATION: On May 19, 1977, the NRC published in the Federal Register (42 FR 25743) proposed amendments to its regulations pertaining to the human uses of byproduct materials including teletherapy units. The proposed amendments to § 35.13 would have required teletherapy licensees to:

1. Have a qualified expert perform full calibration measurements at least once each year;
2. Perform spot-check measurements on their teletherapy units at least monthly; and
3. Report to NRC if these measurements indicate that patients treated by teletherapy units received a radiation dose differing from the prescribed dose by more than 10 percent.

The public was invited to submit written comments and suggestions on the proposed amendments. The comment period, originally set to close on July 5, 1977, was extended to July 29, 1977.

I. Comments on Proposed Rule

Fifty-nine comments were received. Copies of the comments and a detailed analysis of the comments may be examined in the NRC Public Document Room at 1717 H Street, NW., Washington, D.C. Approximately one-half of the commenters supported the proposed rule. Of the remainder, approximately one-half disapproved of the proposed rule and the other half were non committal. Virtually all of the commenters offered helpful suggestions, most of which were accommodated as detailed in Section II below, *"Summary of Major Changes in the Final Rule"*.

Most of the commenters who disapproved of the proposed rule questioned either the need for a rule or whether NRC was the appropriate federal agency to require calibrations of teletherapy units.

The Commission agrees with those commenters who pointed out that the Riverside Hospital incident involving 400 patients was an isolated case and that NRC's efforts to alert other licensees and check on their calibrations were successful. However, the Commission believes that the Riverside incident evidences the magnitude of the harm which could be caused by a single uncalibrated teletherapy unit. The purpose of this rule is to ensure that teletherapy units remain properly calibrated throughout their useful lives.

Those commenters who questioned whether NRC was the appropriate agency to require calibration of teletherapy units, pointed to potential conflicts with the Food and Drug Administration's (FDA) new authority under the Medical Device Amendments of 1976. Through the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended, NRC has direct regulatory control over the human use of byproduct material in teletherapy units. NRC is the only Federal Agency with *direct* regulatory control over the *use* of byproduct material and, as such, is certainly an appropriate agency to require calibration of NRC regulated teletherapy units. NRC is aware that its responsibilities and those of FDA do overlap in the area of medical devices. NRC and FDA staff members have met on several occasions to coordinate the responsibilities of the two agencies. It appears that it will be some time before the FDA has standards or guidelines in place for teletherapy calibration. As they are developed, NRC will work closely with FDA to minimize overlapping regulation by the two agencies.

One commenter suggested that licensees be required to participate in calibration check programs such as those sponsored by FDA or the National Bureau of Standards. The Commission encourages teletherapy licensees to participate in voluntary calibration check programs but will not require it.

Several commenters did not understand that a qualified expert need not actually perform the spot-check measurements. The final rule states clearly that the qualified expert need not actually perform the spot check, but the results of the measurements must be reviewed by a qualified expert within 15 days.

There were numerous comments on the section of the proposed rule that would have required reporting to NRC, and to the patient's referring physician, certain misadministrations involving teletherapy units. The misadministration reporting requirement in the proposed teletherapy calibration rule has been deleted from the final rule. All comments received on this subject will be considered as comments on the more comprehensive proposed misadministration reporting requirement that was published in the FEDERAL REGISTER on July 7, 1978 (43 FR 29297), for public comment.

II. SUMMARY OF MAJOR CHANGES IN THE FINAL RULE

NRC has decided to issue the final rule by adding §§ 35.21-35.25, inclusive, to 10 CFR Part 35, rather than by amending § 35.13 as proposed. This change will make the final rule easier to read and understand. It will also be clear that the rule pertains only to teletherapy units and not to other sealed sources.

As discussed in Section I above, the misadministration reporting requirement of the proposed rule has been deleted.

Section 35.21 on full calibration has been expanded to require full calibration following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly and prior to treating humans. In § 35.21 the term "significant change," which related to the spot-check measurement and will trigger a recalibration, now reads "output differs by more than 5 percent." Section 35.21 now includes a performance standard of "to an accuracy within ± 3 percent" for the calibration of teletherapy output. Finally, § 35.21 now includes a requirement to correct the calibration of teletherapy output for physical decay at intervals not to exceed one month.

Under the effective rule, the licensee generally will not have to submit the training and experience of the qualified expert to NRC for evaluation. Rather, § 35.24 requires the licensee to determine, pursuant to the provisions of that section, if a person is an expert qualified by training and experience to calibrate teletherapy units. The licensee will then keep records of that evaluation of the expert's training and experience for inspection by NRC.

A new requirement has been added to ensure that dosimetry systems used to calibrate the teletherapy units are also properly calibrated. Section 35.23 requires that the dosimetry system used for full calibrations has itself been calibrated by the National Bureau of Standards (NBS) or by one of three Regional Calibration Laboratories (RCL), who in their turn are directly "traceable" to NBS. Alternatively, a dosimetry system used solely for spot-check measurements may be calibrated by direct intercomparison with a system calibrated by NBS or one of the RCLs.

III. FINAL RULE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and Sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 35, are published as a document subject to codification.

10 CFR Part 35 is amended by adding a new center heading and new §§ 35.21-35.25, as follows:

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44 FR 10358
Published 2/20/79
Effective 3/22/79

PART 35—HUMAN USES OF BYPRODUCT MATERIAL

Change in License Conditions for Certain Medical Licenses

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations (a) to permit physicians greater latitude, when they use certain low risk diagnostic radiopharmaceuticals, by no longer designating authorized clinical procedures and (b) by deleting from several licensing groups certain chemical forms not approved by FDA.

EFFECTIVE DATE: The amendment becomes effective on March 22, 1979.

FOR FURTHER INFORMATION CONTACT:

Edward Podolak, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (Phone: 301-443-5860).

SUPPLEMENTARY INFORMATION: On March 17, 1978, the NRC published for a 60-day comment period a proposed rule (43 FR 11206) to amend its regulations to delete the specification of the diagnostic clinical procedures from the lists of radiopharmaceuticals in Groups [1] I, II, and III of § 35.100. In the same proposal an amendment to § 35.14 would require physicians to follow the product

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[1] The most common types of NRC specific licenses for the medical uses of byproduct material are the *Group* medical licenses under § 35.14 that apply to those radioactive materials listed in § 35.100. The radioactive materials listed in § 35.100 are divided into six groups, each group having similar requirements for user training and experience facilities and equipment, and radiation safety procedures. Groups I, II and III are lists of radiopharmaceuticals for diagnostic procedures; Groups IV and V are lists of radiopharmaceuticals for therapeutic procedures; and Group VI is a list of radioactive medical devices for both diagnostic and therapeutic procedures.

labeling for the chemical and physical form, route of administration and recommended dosage range *when* they use Groups I, II and III radiopharmaceuticals for clinical procedures not specified in the product labeling. In the same proposal the Commission also proposed to update the lists in Groups I, II and III by deleting certain chemical forms not approved by the Food and Drug Administration (FDA).

Copies of the proposed rule were sent to all NRC medical licensees, the States and 25 professional societies and individuals. Eighteen comment letters were received. Seven commenters favored the proposal without qualification. Seven commenters favored the proposal but suggested a change. Three commenters objected to the proposal. One commenter discussed a point that was beyond the scope of the proposal but will be considered by NRC separately.

DISCUSSION OF MAJOR COMMENTS

The comments favoring the proposal but suggesting a change suggested that NRC should not restrict physicians to follow the product labeling for the chemical and physical form, route of administration and recommended dosage range when using radiopharmaceuticals for clinical procedures not specified in the product labeling. Most of these commenters felt that the route of administration should be left to the physician. The example cited most often was the administration of Tc-99m pertechnetate orally or rectally when it has been approved by FDA only for intravenous administration. These commenters state that the oral or rectal route might, in some instances, be safer than intravenous administration, for example, in an emergency situation or when a vein is not available for injection. One commenter suggested that agents approved by FDA for intravenous injections should be allowed to be injected into the venous side of the circulation through an in-swelling heart catheter or even into the pulmonary arterial circulation through a Swan-Ganz catheter. Two commenters pointed out that FDA does not restrict the physician to the chemical and physical form route of administration or recommended dosage range in the product labeling. One commenter expressed concern that the NRC restrictions would hinder research into new uses and dosage forms.

Some of these commenters who suggested that NRC should not restrict the route of administration and dosage range erroneously assumed that these restrictions also applied when using drugs for clinical procedures specified in the product labeling. With the exception of the restriction on the chemical and physical form of the radiopharmaceutical, which will still be specified in the § 35.100 Groups, the NRC restrictions on route of administration and dosage range apply *only* when physicians use a radiopharmaceutical for clinical procedures not specified in the product labeling. Stated alternatively, physicians may depart from the product labeling regarding dosage range and route of administration when they follow that labeling regarding the FDA-approved clinical procedure. This policy is consistent with FDA's recognition that good medical practice requires physicians to be free to use drugs according their best knowledge and judgment in the interest of the patient. The compatibility between NRC and FDA policy in this matter is discussed in detail in the preamble to the proposed regulation (43 FR 11206). The Commission recognizes that holding physicians to the labeled chemical and physical form, labeled route of administration, and labeled dosage range (when they use a radiopharmaceutical for clinical procedures not specified in the product labeling) is more restrictive than FDA. The Commission believes that these restrictions minimize the risk to patients from diagnostic clinical procedures that have not been approved by FDA.

Regarding the comment about hindering research, each of the Groups I, II, and III includes a provision authorizing the use of products for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the FDA. Research may also be conducted under NRC licenses of broad scope provided the studies are performed in accordance with FDA regulations and are approved by the licensee's Medical Isotopes Committee.

One commenter who disapproved of the proposed rule believes that the existing rule provides adequate control and should not be changed. Another commenter challenged the assumption that physicians always use their best knowledge and judgment when using drugs for unapproved uses. This commenter noted that the patient is generally totally incompetent to judge whether the benefit of a procedure exceeds the risk and that the proof of damage generally rests with the patient. The this commenter who disapproved of the proposed rule questioned how the benefit-risk decision would be made by the physician. These commenter wanted to know if the procedure is automatically warranted when there is an expectation that the procedure will yield some useful diagnostic information.

In answer, the Commission believes that the use of diagnostic radiopharmaceuticals listed in Groups I, II and III for clinical procedures not yet approved by FDA entails low risk to the patient, provided the chemical and physical form, route of administration and the dosage range remain the same as specified in the radiopharmaceutical labeling. Advances in medical knowledge and practice inevitably precede labeling revision by the manufacturer and formal label approval by the FDA. Good medical practice and patient interests are best served when the physicians are free to use radiopharmaceuticals to their best knowledge and judgment, notwithstanding the opportunity for abuse of this freedom by some physicians.

The text of the final rule has not changed from the text of the proposed rule except for: (1) The additions of some chemical forms that have been added to the § 35.100 groups through previous FEDERAL REGISTER notices; and (2) the names of some chemical forms have been changed to conform with FDA guidelines (e.g., "diethylenetriaminepentaacetic acid" is now called "pentatate sodium").

Under the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and Sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 35 are published as a document subject to codification.

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45 FR 31701
Published 5/14/80
Effective 11/10/80

10 CFR Part 35

Misadministration Reporting Requirements

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Final rule.

SUMMARY: The NRC is amending its regulations to require its licensees to: (1) keep records of all misadministrations of radioactive material; (2) promptly report therapy misadministrations to the NRC, the referring physician, and the patient or the patient's responsible relative (or guardian); and (3) report diagnostic misadministrations quarterly to NRC.

EFFECTIVE DATE: November 10, 1980.

Note.—NRC has submitted this rule to the Comptroller General for review under the Federal Reports Act, as amended, 44 U.S.C. 3512. The date on which the rule becomes effective reflects inclusion of the 45-day period that the statute allows for this review (44 U.S.C. 3512(c)(2)).

FOR FURTHER INFORMATION CONTACT: Edward Podolak, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (Telephone: 301–443–5860).

SUPPLEMENTARY INFORMATION: On July 7, 1978, NRC published in the **Federal Register** (43 FR 29297) a proposed rule on the misadministration of radioactive material to patients. The proposed § 35.33 would have required medical licensees to do three things:

(1) Keep records of all

misadministrations for 5 years;

(2) Promptly report all therapy misadministrations and those diagnostic misadministrations that could cause a clinically detectable adverse effect to: NRC, the referring physician, and the patient or a responsible relative (unless the referring physician stated that the information would harm them); and

(3) Follow the prompt report with a written report to NRC and the patient or responsible relative within 15 days.

In the proposed rule, a misadministration was defined as the administration of:

(1) A radiopharmaceutical or radiation from a source other than the one intended;

(2) A radiopharmaceutical or radiation to the wrong patient;

(3) A radiopharmaceutical or radiation by a route of administration other than that intended by the prescribing physician;

(4) A diagnostic dose of a radiopharmaceutical differing from the prescribed dose by more than 20 percent; or

(5) A therapeutic dose of a radiopharmaceutical or exposure from a radiation source such that the total dose or exposure differs from the prescribed dose or exposure by more than 10 percent.

The public was invited to submit written comments and suggestions on the proposed rule. The proposed rule was mailed to all medical licensees, about 30 professional and public-interest groups, and 2,000 state and county medical societies.

Comments on Proposed Rule

The Commission received 150 letters commenting on the proposed rule. Copies of these letters, a summary and analysis of the comments, and the value/impact analysis supporting the final rule are available for public inspection at the Commission's Public Document Room at 1717 H Street, NW., Washington, D.C. Single copies of the summary and analysis of the comments or value/impact analysis may be obtained from Edward Podolak at the above address.

Ninety percent of the comments were opposed to the rule, most citing it as an unprecedented intrusion into medical practice. Basically, the commenters were opposed to misadministration reporting to NRC where reports would be open to public scrutiny, and misadministration reporting to patients which they felt would cause "undue alarm" and "unwarranted malpractice suits." Many commenters offered helpful suggestions which were incorporated into the final rule as explained below under *"Summary of Major Changes in the Final Rule."*

Many commenters questioned the need for a misadministration reporting rule. They cited the low number of reported misadminstrations. They stated that misadministrations of radioactive material were less frequent than misadministrations of other drugs or types of therapy. And they noted that there are no similar reporting requirements in medical practice.

The Commission's purpose in requiring misadministration reports to NRC is to identify their causes in order to correct them and prevent their recurrence. The Commission can do this by notifying other licensees if there is a possibility that they could make the same errors. The commission can also change its regulations to prevent specific errors. The significance of a diagnostic misadministration goes beyond the unnecessary radiation exposure if it results in misdiagnosis. Apparently isolated incidents at individual medical institutions could reveal a generic problem when compared nationally.

Examples of rule changes resulting from misadministrations are: a rule requiring annual calibration of teletherapy units (44 FR 1722), and a rule requiring radiation surveys of patients following removal of implants (43 FR 55345).

The Commission does not know the entire extent of misadministrations of radioactive material. In 1976 NRC investigated an incident where 400 therapy patients had received radiation doses exceeding the prescribed doses by as much as 41 percent. In 1977 NRC received seven reports of misadministrations ranging from minor misadministrations to a serious teletherapy overexposure. In 1978 NRC received eleven reports of misadministrations, one of them a serious misadministration of four Ir–192 seeds that were left in a patient. In 1979 NRC has received a single report of a misadministration; colloidal P–32 was administered instead of soluble P–32. The Commission does not know what fraction of the actual incidence of misadministrations these reports represent. However, whenever there has been a serious misadministration, the Commission has been able to act to help prevent recurrence by issuing notices or orders to licensees or through rulemaking.

The Commission recognizes that its misadministration reporting requirement may be unique to medical practice. The Commission also recognizes that the misadministration of radiopharmaceuticals and radiation from sealed sources may be less frequent than the misadministration of other drugs or forms of therapy, because the radiopharmaceutical doses and radiation doses can be measured before administration to patients. However, the Commission believes that the misadministration recordkeeping and reporting requirement is necessary to protect patients.

Many commenters were concerned about the privacy of patients' records when misadministrations are reported to a third party such as NRC.

The final rule states that the patient's name should not be reported to NRC. The reports of misadministrations would be available for public review but without information that would lead to identification of the patient.

The vast majority of the commenters consider the proposed rule as a serious intrusion into the physician-patient relationship. They contend that the proposed rule is an intrusion of a regulatory agency into the care of a patient without assuming responsibility for that care. Many commenters pointed out that the misadministration reporting requirement was unique in medical practice and noted that NRC regulations did not apply to X-rays, accelerator or radium therapy, and accelerator-produced radiopharmaceuticals.

The Commission recognizes the intrusion into the physician-patient relationship in the sense that the rule does affect, to a limited degree, the nature of the physician's obligation to his or her patient—it imposes in certain circumstances an obligation on the physician to report information to the patient and the NRC. For many in the health professions, this limited involvement may be understood, rightly or wrongly, as foreshadowing some greater degree of Governmental involvement or as symbolizing some general movement toward more regulation of the profession.

The Commission does not believe, however, that this limited intrusion warrants abandoning the rule. Some physicians do support the rule—the medical profession is not unanimous that the rule would constitute an unwarranted intrusion into the physician-patient relationship. The "physician-patient" relationship is a concept that was developed to advance the needs of the patient. The relationship involves duties of reasonable care and skill, confidentiality, and good faith owed by the physician to the patient. Nothing in the rule would detract from these duties. Thus, in a strict sense, the rule would not interfere with the relationship.

It is true that no similar reporting requirements are attached to use of X-rays, accelerator or radium therapy, or accelerator-produced isotopes. However, this is the direct result of limitations in NRC's regulatory authority. At present, unless Congress should expand NRC's authority, the NRC must operate under the presumption that Congress intended that a disproportionate degree of Federal regulatory control be exercised over nuclear materials as opposed to these other sources of radiation.

In many respects the adverse comments track those received by the Food and Drug Administration (FDA) in response to a request for comments to help FDA formulate a policy on labeling of prescription drug products to promote patient understanding of the nature and effects of the drugs prescribed for them. In a notice of proposed rulemaking (44 FR 40016, July 6, 1979), the FDA rejected the assertion that mandatory patient labeling would constitute an unwarranted interference in the physician-patient relationship, pointing out among other things that a patient has a right to know about a drug's benefits, risks, and directions for use.

Also, in a January 1979 report (EMD-79-16), the General Accounting Office (GAO) stated:

> In our view, requiring medical licensees to report misadministrations to NRC is not an intrusion into medical practice. This is clearly consistent with NRC regulatory responsibilities and a necessary part of an effective nuclear medicine regulatory program. Without this kind of feedback on incidents affecting the public health and safety, NRC cannot be sure it is adequately regulating the possession and use of nuclear materials in medical practice.

Many commenters were concerned that the proposed rule, particularly the patient reporting requirement, would invite unwarranted malpractice suits and thereby boost medical costs. Some of these commenters suggested that the rule would lead to covering up misadministrations to avoid liability.

The Commission believes that the requirement in the final rule to report therapy misadministrations to patients or a responsible relative is important. Patients have a right to know when they have been involved in a serious misadministration, unless this information would be harmful to them. NRC has parallel requirements for licensee reports to workers on occupational overexposures. Also, there is a trend in Federal legislation that recognizes the right of individuals to know information about themselves which is contained in the records of institutions both inside and outside of the Federal sector. Examples are: the Privacy Act of 1974, which set rules for Federal Agencies' recordkeeping; the Fair Credit Reporting Act and related acts, which gave consumers the right to know information about themselves contained in the records of credit-reporting bureaus; and the Family Education Rights and Privacy Act, which gave students the right to see personal records held by educational institutions. Also, in April 1979, the President sent the proposed "Privacy of Medical Information Act" to Congress, and President said:

> The "Privacy of Medical Information Act" is being submitted to you today. It establishes privacy protections for information maintained by almost all medical institutions. The Act will give individuals the right to see their own medical records. If direct access may harm the patient, the Act provide that access may be provided through an intermediary. This legislation allows the individual to ensure that the information maintained as part of his medical care relationship is accurate, timely and relevant to that care. Such accuracy is of increasing importance because medical information is used to affect employment and collection of insurance and other social benefits. * * *

Regarding the comment that the rule would invite malpractice suits and thereby boost medical costs, this may well be true. The amount of this increase is not known. In response to NRC query, the National Association of Insurance Brokers replied:

> It is simply beyond our competence to quantify the effect on medical malpractice rates of your proposed rule. * * * that the proposed change would have an adverse effect on rates seems indisputable, since the doctors would be required, in a sense, to prepare testimony against themselves. We frankly doubt that anyone can gauge the likely effect of such a rule * * *

Regarding the suggestion that the rule would lead to covering up misadministrations to avoid liability, the Commission does not believe that physicians would willfully disregard the rule. Moreover, there is nothing in the rule that would in any way modify the legal rules governing malpractice suits arising out of reported misadministrations.

A majority of the commenters who opposed the rule were opposed to the requirement for reporting diagnostic misadministrations to patients. They stated that most misadministrations of diagnostic radiopharmaceuticals would not harm the patient. They also stated that the definition of a diagnostic misadministration as an error greater than 20 percent would unduly alarm the patient because it was too low. They stated that the recommended dosage ranges in the drug labeling spanned factors of two and greater. They further stated that the standard dosages vary between institutions by as much as 100 percent. They also stated that this definition discriminated against short half-life radiopharmaceuticals which give a smaller radiation dose to the patient.

The proposed rule had a threshold for reporting diagnostic misadministrations. The threshold was not clear. The proposed rule required reporting of all therapy misadministrations and those diagnostic misadministrations that could cause a "clinically detectable" adverse effect on the patient.

The staff agrees that the definition of a diagnostic misadministration as a 20 percent error is too low. That level was chosen originally because it was within the state-of-the-art for radiopharmaceutical measurement and the Commission was concerned that the limit for a diagnostic misadministration would be construed as good practice. The Commission recognizes that there are factors, such as patient scheduling, which are not errors but could cause the patient to receive a dose differing from the prescribed dose by more than 20 percent without affecting the effectiveness of the test. The final rule defines a diagnostic misadministration, in part, as that differing from the prescribed dose by more than 50 percent. At this limit of 50 percent: (1) an error has obviously occurred and (2) 50 percent over or under the prescribed dose can clearly compromise the effectiveness of the diagnostic procedure.

Some commenters objected to the absence of a definition for a "clinically detectable adverse effect" in the threshold for reporting diagnostic misadministrations. Others questioned who would make that determination. Others objected to the physician having too much leeway in making the determination. Still others complained that, without guidelines, they would have difficulty in making the determination.

At the proposed rule stage, the Commission believed that "clinically detectable" was a term well understood in medicine. According to some commenters, this is not the case. The Commission recognizes that the diagnosis of an "adverse effect" may in one case be based on a single dramatic symptom, while in another case it may be based on a number of individually minor deviations from the normal for that patient. Because of this and because adverse effects may be delayed in time, the term "clinically detectable adverse effect" is a moving target. Therefore, the Commission is abandoning this term and the threshold. The final rule will require reporting of all diagnostic misadministrations to NRC.

Several commenters questioned whether extravasation is considered a misadministration.

Extravasation is the infiltration of injected fluid into the tissue surrounding a vein or artery. Extravasation frequently occurs in otherwise normal intravenous or intraarterial injections. It is virtually impossible to avoid. Therefore, the Commission does not consider extravasation to be a misadministration.

Some commenters questioned whether they would have to measure the activity in a syringe before and after the injection in order to determine if a misadministration has occurred.

Misadministrations of a radiopharmaceutical is defined as a percentage error from the prescribed dose. It is necessary to measure the activity prior to injection and then inject the contents of the syringe. It is not necessary to measure the residual activity in the syringe.

One commenter suggested that licensees be required to keep records of misadministrations for 50 years. Instead of the proposed 5 years, because of the long latency period for radiation-induced cancers. For the same reason, another commenter suggested that the records be maintained for 30 years.

The Commission agrees that there are compelling reasons for insuring that the records of misadministrations should be maintained for a period of time longer than the five years as originally proposed. At the same time it is not yet clear for what specific length of time NRC should require these records to be maintained by the licensee.

As an alternative to requiring licensees to maintain misadministration records for any specific length of time, the final rule requires that licensees shall preserve misadministration records until the Commission authorizes disposition. This approach is consistent with Part 20.401 of NRC's regulations which requires that NRC licensees maintain and preserve radiation exposure records for monitored personnel until the Commission authorizes disposition.

Under the provisions of section 208 of the Energy Reorganization Act of 1974, the Commission reports each quarter to the Congress on any abnormal occurrences involving facilities and activities regulated by the NRC. An abnormal occurrence is defined in section 208 as an unscheduled incident or event which the Commission determines is significant from the standpoint of public health or safety. The Commission published a policy statement on abnormal occurrence reporting in the **Federal Register** (42 FR 10950). Those misadministrations which the Commission determines meet the criteria for abnormal occurrence reporting will be published in the quarterly "Report to Congress on Abnormal Occurrences." In the past, teletherapy overexposures have been reported to Congress in this manner.

Summary of Major Changes in the Final Rule

The final rule was organized into separate sections, specifically §§ 35.41 through 35.45, to make the requirements easier to understand.

Several commenter's suggestions were incorporated into the final rule. As noted above, the term "could cause a clinically detectable adverse effect" in the threshold for reporting diagnostic misadministrations has been abandoned in the final rule. Instead, all diagnostic misadministrations will be reported quarterly to NRC only. These reports of diagnostic misadministrations are to be in letter format and postmarked not later than 10 days following the calendar quarters ending in March, June, September, and December.

The Commission encourages licensees to report diagnostic misadministrations to patients but does not believe that the risk of a diagnostic misadministration warrants Federal intervention in this decision. Therefore, the Commission will not require licensees to report diagnostic misadministrations to the patient or relative (or guardian).

In the final rule, only therapy misadministrations are required to be reported to the referring physician and the patient or responsible relative. There are two changes regarding notification of the patient or responsible relative in § 35.42(a). First, a parenthetical "(or guardian)" was added to "responsible relative" to cover persons who do not have relatives. Second, now the referring physicians, if they wish, may inform the patient of the misadministration.

In the final rule, the limit for a diagnostic misadministration in § 35.41 has been raised to errors greater than 50 percent. Many commenters pointed out that the recommended dosages in radiopharmaceutical labeling cover ranges of up to a factor of 10 and that, comparing nuclear medicine departments, there is often a 100% or greater difference in the standard dosages for the same procedure. The Commission did not raise the limit of error for a diagnostic misadministration above the 50% level because this level begins to affect the quality of the diagnostic procedures. A poor quality diagnostic procedure could require a re-take or could result in a misdiagnosis.

In The final rule, the definition of a therapy misadministration in § 35.41 (e) and (f) distinguishes between radiopharmaceutical therapy and sealed source therapy. For sealed source therapy, the new definition recognizes that the therapist often adjusts the dose during treatment. Also, the new definition recognizes that the radiation dose in sealed source therapy is calculated as a function of dose rate, time, and treatment geometry, and is not usually measured directly. These changes resulted from several comments from radiation therapists.

Final Rule

Under the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and Sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 35, are published as a document subject to codification.

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45 FR 41393
Published 6/19/80
Effective 9/2/80

Testing of Radioisotope Generators

See Part 30 Statements of Consideration

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47 FR 12939
Published 3/26/82
Effective 3/26/82

10 CFR Part 35

Group Licensing for Certain Medical Uses

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to add a new reagent kit, used to prepare the radiopharmaceutical technetium-99m labeled disofenin, to its list of authorized radioactive drugs and reagent kits. NRC is taking this action because the Food and Drug Administration (FDA) recently approved a "New Drug Application" for this reagent kit.

EFFECTIVE DATE: March 26, 1982.

FOR FURTHER INFORMATION CONTACT: Elizabeth G. Rodenbeck, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, (Telephone 301–427–4580).

SUPPLEMENTARY INFORMATION: Notice is hereby given of the amendment of the Nuclear Regulatory Commission's regulation, "Human Uses of Byproduct Material," 10 CFR Part 35.

Section 35.100 of 10 CFR Part 35 lists groups of medical uses of byproduct material that have similar requirements for user training and experience, facilities and equipment, and radiation safety procedures. The purpose of this grouping is to reduce administrative costs by eliminating the need for licensees to seek an amendment to their license each time they wish to use an additional radiopharmaceutical in a group for which they are licensed. As new radiopharmaceuticals, sources, devices, and uses are developed and approved by FDA, they are added to the appropriate group in § 35.100. The FDA has recently approved a "New Drug Application" for a reagent kit that is used to prepare the radiopharmaceutical, technetium-99m labeled disofenin, and the use of this reagent kit is hereby added to Group III.

As described in NRC's medical policy statement that was published in the Federal Register on February 9, 1979 (44 FR 8242), the NRC relies on FDA for approval of safety and effectiveness of radioactive drugs. The Commission has found that good cause exists for omitting notice of proposed rulemaking and public procedure thereon, because it would be contrary to the public interest to delay the use of this FDA-approved product by group medical licensees. Since the amendment relieves licensees from restrictions under regulations currently in effect, it may become effective without the customary 30-day notice.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and section 553 of Title 5 of the United States Code, the following amendments to Title 10 Chapter I, Code of Federal Regulations, Part 35 are published as a document subject to codification.

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47 FR 28087
Published 6/29/82
Effective 6/29/82

10 CFR Part 35

Group Licensing for Certain Medical Uses

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to add a new reagent kit, used to prepare the radiopharmaceutical technetium-99m labeled succimer, to its list of authorized radioactive drugs and reagent kits. NRC is taking this action because the Food and Drug Administration (FDA) recently approved a "New Drug Application" for this reagent kit.

EFFECTIVE DATE: June 29, 1982.

FOR FURTHER INFORMATION CONTACT: Elizabeth G. Rodenbeck, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (Telephone 301–427–4580).

SUPPLEMENTARY INFORMATION: Notice is hereby given of the amendment of the Nuclear Regulatory Commission's regulation, "Human Uses of Byproduct Material," 10 CFR Part 35.

Section 35.100 of 10 CFR Part 35 lists groups of medical uses of byproduct material that have similar requirements for user training and experience, facilities and equipment, and radiation safety procedures. The purpose of this grouping is to reduce administrative costs by eliminating the need for licensees to seek an amendment to their license each time they wish to use an additional radiopharmaceutical in a group for which they are licensed. As new radiopharmaceuticals, sources, devices, and uses are developed and approved by FDA, they are added to the appropriate group in § 35.100. The FDA has recently approved a "New Drug Application" for a reagent kit that is used to prepare the renal imaging radiopharmaceutical, technetium-99m labeled succimer (also known as DMSA), and the use of this reagent kit is hereby added to Group III.

As described in NRC's medical policy statement that was published in the Federal Register on February 9, 1979 (44 FR 8242), the NRC relies on FDA for approval of safety and effectiveness of radioactive drugs. The Commission has found that good cause exists for omitting notice of proposed rulemaking and public procedure thereon, because it would be contrary to the public interest to delay the use of this FDA-approved product by group medical licensees. Since the amendment relieves licensees from restrictions under regulations currently in effect, it may become effective without the customary 30-day notice.

List of Subjects in 10 CFR Part 35

Byproduct material, Drugs, Health facilities, Health professions, Medical devices, Nuclear materials, Occupational safety and health, Penalty, Radiation protection, Reporting and recordkeeping requirements.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and Section 553 of Title 5 of the United States Code, the following amendments to Title 10 Chapter I, Code of Federal Regulations, Part 35 are published as a document subject to codification.

≫47 FR 40149
Published 9/13/82
Effective 9/13/82

10 CFR Part 35

Institutional Radiation Safety Committee

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations regarding hospitals licensed to use radioactive byproduct material for human applications. Currently, such a license requires that the hospital have a Medical Isotopes Committee to review clinical aspects of the use of radioactive materials within the hospital. The amendment requires instead a Radiation Safety Committee with a simplified membership that will focus on the radiation safety of workers and the general public. The rule change acknowledges the Food and Drug Administration's role in regulating the safety and effectiveness of radioactive drugs with respect to the patient. The membership of the new Radiation Safety Committee will include the hospital management and the nursing staff in decisions affecting radiation safety at the hospital and will be easier for smaller hospitals to recruit.

EFFECTIVE DATE: October 12, 1982.

FOR FURTHER INFORMATION CONTACT: Elizabeth G. Rodenbeck, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Telephone (301) 427–4580.

SUPPLEMENTARY INFORMATION: A proposed amendment (44 FR 21023) was published in the Federal Register on April 9, 1979 that would change the Medical Isotopes Committee in § 35.11(b) to a Radiation Safety

Committee, change the function to coordinating and supervising the institution's radiation safety program, and change the membership to include a specialist from each department using radioactive material, a representative of the nursing staff, a representative of the institution's management, and a person trained in radiation safety.

A change in the Medical Isotopes Committee concept is needed for several reasons. (1) The use of radiopharmaceuticals is now governed by the FDA through the package insert that describes routine uses. Institutional group medical licensees use FDA-approved radiopharmaceuticals for the routine procedures listed in § 35.100 groups. The NRC reviews and approves the qualifications of physician-users before granting institutional licenses. With these controls to ensure patient radiation safety, a Medical Isotopes Committee is no longer needed to approve uses of radiopharmaceuticals for group licensees. (2) A representative of the institution's management is included on the committee as the member with the authority to commit resources in the name of the institution for resolving safety problems, and to provide management concurrence in enforcement of radiation safety rules. (3) Including a representative of the nursing staff on the committee provides nurses an opportunity to identify and help resolve problems in the care of ward patients who have received radioactive drugs and keeps the nursing staff fully informed on all aspects of the radiation safety program.

Comments on the Proposed Rule

The Commission received 60 letters commenting on the proposed rule. Copies of these letters, a summary and analysis of the comments, and the value/impact analysis supporting the final rule are available for public inspection at the Commission's Public Document Room at 1717 H Street, NW, Washington, D.C. The majority of the comments addressed the following two issues:

1. The change will compromise the medical supervision of research activities using radioactive drugs that are performed by broad scope programs.

Response: The large medical research centers with broad scope medical licenses in the Type A category are already required by § 33.13(c)(1) to appoint a Radiation Safety Committee. In addition, human research uses radionuclide tracers by all medical licensees are monitored by the Radioactive Drug Research Committee mandated by the Food and Drug Administration (FDA) in 21 CFR 361.1(b)(1). The Commission believes that the broad scope medical program is adequately monitored by the combined oversight of the NRC's Radiation Safety Committee and the FDA's Radioactive Drug Research Committee.

2. Requiring a specialist from each department using byproduct material would make the committee very large and unwieldy for medical licensees with many user departments throughout an institution.

Response: The wording of the amendment has been revised to require an authorized user for each type of use permitted by the license. This change will (1) assure physician representation since users authorized for human use of byproduct material are physicians and (2) limit the representation to each type of byproduct use to keep the committee to a manageable size.

The Final Rule

The final rule differs slightly from the proposed rule. The simple term "oversee" has been substituted for the phrase "maintain surveillance over." Appendix B of Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Programs," provides specific guidance on the responsibilities and duties of the Medical Isotopes Committee which will be assumed by the Radiation Safety Committee. Additional guidance on specific radiation safety procedures is available in Regulatory Guide 8.18, "Information Relevant to Ensuring That Occupational Radiation Exposures at Medical Institutions Will Be As Low As Reasonably Achievable," and NUREG-0267, "Principles and Practices for Keeping Occupational Radiation Exposures at Medical Institutions As Low As Reasonably Achievable." To keep the committee to a manageable size the wording of the rule has been changed to require "an authorized user for each type of use permitted by the license." The institution's "Radiation Safety Officer" has been specified as the primary person trained in radiation safety. For very small programs, an authorized user may also serve as the Radiation Safety Officer.

As mentioned in the preamble to the proposed rule and consistent with current licensing practice, the NRC will not require submission of a license amendment each time there is a change in committee membership. Instead, institutional licensees will document the names and qualifications of the committee members for their own files, will update the information as necessary, and will keep the records available for Commission inspection.

The wording "at least the following" in the rule is intended to encourage licensees to add members depending on the unique needs of the institution.

Although it seems unlikely that a medical institution performing radioisotope procedures on patients would not have nurses, any licensee who cannot meet the requirement for a nurse representative may request a specific exemption from this requirement under the provision of 10 CFR 30.11(a). A request for an exemption should be addressed to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

For broad scope medical licensees only one Radiation Safety Committee is required if the membership reflects the requirements in both §§ 33.13(c)(1) and 35.11(b).

Licensees may use the Radiation Safety Committee to oversee the safety of all sources of radiation throughout the medical institution; however, NRC authority is limited to byproduct material.

Paperwork Reduction Act Statement

Note that this final rule contains no new or amended requirements for recordkeeping, reporting, plans or procedures, applications, or any other type of information collection.

List of Subjects in 10 CFR Part 35

Byproduct material, Drugs, Health facilities, Health professions, Medical devices, Nuclear materials, Occupational safety and health, Penalty, Radiation protection, Reporting and recordkeeping requirements.

Under the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and section 553 of title 5 of the United States Code, the following amendment to Title 10, Chapter 1, Code of Federal Regulations, Part 35, is published as a document subject to codification.

≫ 48 FR 2115
Published 1/18/83
Effective 3/4/83

Teletherapy Room Radiation Monitors and Inspection and Servicing of Teletherapy Source Exposure Mechanisms

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations applicable to NRC teletherapy licensees. The intent of these amendments is to ensure prior warning to the operator in the event of a malfunction of a teletherapy source

exposure mechanism and to ensure adequate inspection and servicing of the teletherapy machine. The amendments require:

1. The installation of radiation monitors in teletherapy rooms;

2. The use of portable survey instruments or audible alarm personal dosimeters whenever the permanent radiation monitors are inoperable; and

3. The inspection and servicing of all teletherapy units to assure proper functioning of the source exposure mechanism, during source replacement or at intervals not to exceed five years, whichever comes first.

EFFECTIVE DATE: March 4, 1983.

FOR FURTHER INFORMATION CONTACT: Mr. Alan K. Roecklein, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (301-443-5970).

SUPPLEMENTARY INFORMATION: In May 1980, the Office of Nuclear Material Safety and Safeguards issued orders to all NRC teletherapy licensees requiring the installation of teletherapy room radiation monitors and the use of portable radiation survey meters when the installed monitors are inoperable. In 1972 the NRC established a standard teletherapy license condition requiring inspection and servicing of all teletherapy machines to assure proper functioning of the source exposure mechanisms at time of source replacement or every five years, whichever comes first, and requiring that a record of the inspection and servicing be kept on file for review by the Commission's Office of Inspection and Enforcement. These actions were intended to provide early warning of, and to help prevent, potentially serious over-exposures of teletherapy operators and patients in the event that the source exposure mechanism failed.

The radioactive sources contained in teletherapy units produce radiation fields on the order of hundreds of rads per minute in areas accessible to patients and operators. An undetected exposed source could result in overexposures of patients or operating personnel in a short period of time. Teletherapy units are designed with reliable source handling components. In spite of careful design the NRC is aware of some teletherapy equipment malfunctions that had the potential for causing serious overexposures. Although no overexposures involving serious injury have occurred, the rule changes described in the summary are intended to provide greater assurance that teletherapy equipment malfunctions do not occur and that they will be detected before serious injury can occur.

It is the Commission's intent to codify the previously described orders and license condition, as modified herein, so that they are uniformly applicable to existing licensees and new applicants. A copy of this final rule notice will be sent to all current teletherapy licensees with a cover letter calling the licensees' attention to the matters outlined below.

With regard to the May 7, 1980 orders requiring the installation of radiation monitors, licensees are advised that the orders are hereby rescinded. Most teletherapy licenses now include a license condition that incorporates the provisions of the May 7, 1980 orders. Licensees are advised that the NRC considers the final rule to supersede these license conditions as well. Specifically the rule differs from the previous orders in that it will permit the use of a back-up power supply other than a battery and will also permit the use of audible alarm personal dosimeters as well as portable survey meters if the radiation monitor is inoperable. Licensees are referred to Regulatory Guide 8.28, "Audible Alarm Dosimeters," for guidance concerning the use and limitations of audible alarm personal dosimeters.

Some licensees requested relief from the 1972 license condition requiring five-year inspection and servicing of their units. The NRC staff considered these requests on a case-by-case basis and many of the requests have been granted in the form of a license condition modifying the time interval. It is intended that the license conditions already granted will take precedence over the rule when it becomes effective.

The rule includes a provision to this effect in § 35.26.

Licensees are advised that if, after the rule change is published and becomes effective, there are unusual circumstances, they may request a specific exemption under 10 CFR 30.11. These requests will be considered on a case-by-case basis as a request to amend a license and must be accompanied by the appropriate fee required by 10 CFR 170.31.

Comment Analysis

On April 28, 1982, the Nuclear Regulatory Commission published for comment in the Federal Register (47 FR 18131) proposed amendments to 10 CFR Part 35 of its regulations. Six letters of public comment were received. One letter opposed the rule and five proposed minor changes. As a result of analysis of the public comments received and further staff discussions, two changes have been made in the amendments as proposed.

—Proposed § 35.25(b) required that the visible indicator of high radiation levels must be located so as to be observable by a person entering the room and during operation of the unit. Several commenters observed and the staff has confirmed that most teletherapy treatment facilities are designed with a maze to prevent exposure of the operator during treatment. In many cases this design would require a separate television camera and receiver system in order to observe the visible indicator on the radiation monitor during treatment. This paragraph has been revised to require that the visible indicator be observable by a person entering the treatment room only.

—Proposed § 35.25(e) required that if a radiation monitor is inoperable for any reason, any person entering the teletherapy room shall use a portable survey instrument to monitor for any malfunction of the source exposure mechanism that may have resulted in an exposed or partially exposed source. It was suggested that audible alarm personal dosimeters would be an acceptable alternative to a portable survey instrument. The staff agreed that, if checked daily before use, available audible alarm personal dosimeters would provide adequate warning of an exposed source if the fixed monitor were inoperable. This paragraph has been revised to permit use of an audible alarm personal dosimeter.

Other substantive comments received on the proposed rule were:

—A statement that inspection of the source exposure mechanism is redundant in view of the requirement for monitoring equipment. This comment is rejected for the reason that inspection is intended to prevent malfunctions, while the radiation monitor can only provide warning that a malfunction has occurred;

—A suggestion that teletherapy units should be equipped with improved timing devices to minimize the chances of exposure timing errors. Although the staff recognizes the merit of improved exposure timing devices the staff does not believe that the comment is within the scope of this rulemaking procedure. However, this comment is under consideration for inclusion in a regulatory guide for teletherapy licensing.

—A suggestion that the permanently mounted radiation monitor should be equipped with an audible alarm. Requiring that the radiation monitor be equipped with an audible alarm was considered in the development of this rule. A decision has been made not to include the audible alarm provision. The staff believes that the cost of backfitting an audible alarm is not justified by the marginal increase in safety. Licensees may install an audible alarm in addition to a visible alarm if they so choose. Licensees desiring to use an audible alarm only may request a specific exemption under 10 CFR 30.11. These requests will be considered on a case-by-case basis as a request to amend the license and must be accompanied by the appropriate fee required by 10 CFR 170.31.

Paperwork Reduction Act Statement

This rule was submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act (Pub. L. 96-511; 42 U.S.C. Ch. 15). The recordkeeping requirement contained in this regulation was approved by OMB. OMB approval No. 3150-0010.

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission hereby certifies that this rule will not have a significant economic impact on a substantial number of small entities.

About 440 teletherapy licensees are regulated by the NRC. Fewer than 1% of these can qualify as small entities for the purposes of the Regulatory Flexibility Act applying the standards contained in 13 CFR Part 121, Small Business Size Standards. All but a few of the teletherapy licensees are hospitals and the Small Business Administration defines small hospitals as having fewer than 150 beds. A check on 104 of NRC teletherapy licensees showed that all of them had more than 150 beds.

The NRC believes that all teletherapy licensees have already installed monitoring equipment and have portable survey instruments available in compliance with the 1980 orders. The cost of an installed monitor and survey instrument is approximately one thousand to fifteen hundred dollars. The approximate cost of a teletherapy unit exceeds one hundred thousand dollars. Annual revenue generated by a teletherapy unit is on the order of 200,000 dollars.

Costs for the inspection, servicing, and recordkeeping will be proportional to the number of units owned by the licensee. An estimate of these costs is less than 500 dollars per year per teletherapy unit.

The Commission believes that the costs to licensees is small compared to the revenue generated by use of a teletherapy unit and that the gains in patient and operator protection will significantly outweigh the economic impact on licensees.

List of Subjects in 10 CFR Part 35

Byproduct material, Drugs, Health facilities, Health professions, Medical devices, Nuclear materials, Occupational safety and health, Penalty, Radiation protection, Reporting requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is adopting the following amendments to 10 CFR Part 35.

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48 FR 5217
Published 2/4/83
Effective 3/7/83

10 CFR Part 35

Physician's Use of Radioactive Drugs

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to provide an exception from certain regulatory requirements for technetium-99m pentetate (a Food and Drug Administration (FDA)-approved drug) used for lung function studies which is a use not yet approved by FDA. Prior to this final rule, NRC regulations required that a physician using an approved drug for an unapproved procedure follow FDA-approved labeling for (1) physical form, (2) route of administration, and (3) dosage range. Because in the lung function studies, technetium-99m pentetate is used as an aerosol and administered by inhalation, it does not meet the FDA-approved method for use of this radiopharmaceutical, and an exception is necessary. The preamble to this rulemaking also sets out the criteria and procedures that NRC will use to evaluate similar requests for exceptions of other diagnostic radiopharmaceuticals. This final rule responds to the petition filed by the late Dr. George V. Taplin to approve the use of technetium-99m pentetate for lung function studies (PRM 35-1). The final rule will relieve many of NRC's medical licensees from applicable regulatory requirements. The final rule and the new exception procedures are intended to remove unnecessary restrictions on the physician in patient treatment while continuing to provide an adequate level of radiation protection for the patient and the worker.

EFFECTIVE DATE: March 7, 1983.

FOR FURTHER INFORMATION CONTACT: Deborah A. Bozik, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC, 20555 (Phone 301-427-4586).

SUPPLEMENTARY INFORMATION: On April 13, 1982, the NRC published a proposed rule (47 FR 15796) to amend its regulations to provide an exception from certain regulatory requirements for technetium-99m pentetate in § 35.14 of 10 CFR Part 35, which contains the specific license requirements for certain groups of medical uses of byproduct material. In addition, this proposed rule also offered criteria and information for evaluation of similar future exceptions to NRC regulations.

This rulemaking was developed in response to a petition filed by George V. Taplin, M.D. (deceased) for a rulemaking to remove NRC restrictions that apply when a physician uses an FDA-approved radioactive drug for a clinical procedure that does not have FDA approval. Specifically, the petitioner sought the nonrestricted use of technetium pentetate as an aerosol for lung function studies (PRM-35-1; 44 FR 25617; May 1, 1979). The NRC grants that portion of the petition that requests a specific exception for technetium-99m pentetate used for lung function studies. The NRC denies the petitioner's request that NRC remove all restrictions on the physican's use of an FDA-approved radioactive drug for a clinical procedure that does not have FDA approval. However, the procedures and criteria established in this rulemaking create an appropriate mechanism for addressing future requests for exceptions to these restrictions and, as such, are an attempt to provide the greater flexibility desired by the petitioner.

The public was invited to submit written comments on the proposed rule by June 14, 1982, and 35 comment letters were received. Thirty-one commenters supported the proposed rule, and 15 specifically noted their support of the criteria and procedures for evaluating similar future exceptions. Copies of the public comments received and the Commission analysis of the comments may be examined in the Commission's Public Document Room at 1717 H Street, N.W., Washington, D.C.

Two commenters opposed the proposed rule because of their feeling that NRC would be authorizing the addition of non-FDA-approved procedures to its regulations, thereby starting a precedent for such procedures to be added without close evaluation. Careful consideration was given to the questions raised by these commenters, but the NRC does not believe that patient protection is being compromised. Technetium-99m penetetate gives several times less radiation to the lung than other radiopharmaceuticals which are more slowly absorbed and thus are retained longer in the lungs. Taplin and Chopra, "Inhalation Lung Imaging with Radioactive Aerosols and Gases," Prog. Nucl. Med., Vol. 5, pp. 119-143 (Karger, Basel 1978), and Taplin and Chopra, "Lung Perfusion-Inhalation, Scintigraphy in Obstructive Airway Disease and Pulmonary Embolism," Radiological Clinics of North America, Vol. XVI, No. 3, pp. 491–513, December 1978.

It is noteworthy that NRC and FDA have sought a solution to the general problem of drug labeling for unapproved uses, and FDA currently is considering a program to add presently unapproved uses of approved radiopharmaceuticals. However, until such a program is implemented, NRC believes that this rulemaking is the most appropriate way to resolve the problem in this interim period. Nine commenters either addressed topics not specifically covered in this rulemaking or requested that NRC consider other unapproved uses of FDA-approved radiopharmaceuticals. The most common requests centered on the uses of technetium-99m pertechnetate for voiding cystograms and technetium-99m sulfur colloid for evaluation of LeeVeen shunt patency. NRC developed criteria and procedures for evaluating exceptions to § 35.14(b)(6). These procedures and criteria were published in the April 13, 1982 proposed rule and were open to the public for comment. They were very favorably received. The Commission will use these criteria to determine whether an exception from the requirements in § 35.14(b)(6) of 10 CFR Part 35 will result in an unreasonable risk to the health and safety of the public or will minimize danger to life or property.

Any interested person should submit a request for an exception to NRC's Office of Nuclear Material Safety and Safeguards detailing the following information.

- Description of the procedures,
- Justification for the exception (including an explanation of why the procedure is not included in the product labelling),
- Purpose and benefits of the procedure,
- Analysis of the radiation dose, and
- Supporting technical and scientific information, including any provisions necessary to ensure occupational safety and patient safety.

In order to reach a conclusion regarding the possible inclusion of these radiopharmaceuticals in the regulations, NRC would expect that such requests would provide evidence that the following two criteria, upon which NRC will conduct its assessment, would be met:

- No unjustified radiation dose to the patient, and
- Demonstration of adequate occupational radiation protection measures.

The NRC staff would review a request, and based upon its findings as well as the recommendation of its Advisory Committee on the Medical Uses of Isotopes (ACMUI), would publish in the Federal Register a notice of rulemaking. The notice would provide for a 30- to 45-day comment period. The final rule establishing the exception would be made immediately effective.

Environmental Impact: Negative Declaration

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in 10 CFR Part 51, that promulgation of this regulation is not a major Federal action significantly affecting the quality of the human environment and therefore an environmental impact statement is not required. The environmental impact appraisal and negative declaration on which this determination is based are available for public inspection at the NRC Public Document Room, 1717 H St. NW., Washington, D.C.

Paperwork Reduction Act Statement

Pursuant to the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501, et seq.), the NRC has made a determination that this rule would not impose new recordkeeping, application, reporting, or other types of information collection requirements.

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission hereby certifies that this rule will not have a significant economic impact upon a substantial number of small entities. The final rule affects about 2,000 specific licenses under §§ 35.11, 35.12, and 35.14 of 10 CFR Part 35. These licenses are issued principally to medical institutions. Small business entities, primarily physicians in private practice, comprise about 275 of the specific medical licenses.

The final rule relieves NRC's medical licensees from regulatory requirements by relaxing restrictions on the physician concerning patient care. The final rule has no significant economic impact on these licensees. In the proposed rule, the NRC specifically requested comments on this conclusion as to impact on small entities. No comments were received that questioned this conclusion.

List of Subjects in 10 CFR Part 35

Byproduct material, Drugs, Health facilities, Health professions, Medical devices, Nuclear materials, Occupational safety and health, Penalty, Radiation protection, Reporting and recordkeeping requirements.

Under the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and section 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 35, are published as a document subject to codification.

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48 FR 8256

Published 2/28/83

10 CFR Part 35

Teletherapy Room Radiation Monitors and Inspection and Servicing of Teletherapy Source Exposure Mechanisms

Correction

In FR Doc. 83–1379 beginning on page 2115 in the issue of Tuesday, January 18, 1983, make the following correction.

On page 2117, third column, § 35.27, ninth line, "export's" should read "expert's".

≫ 48 FR 28431

Published 6/22/83

10 CFR Part 35

Group Licensing For Certain Medical Uses; Albumin Colloid

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to permit licensed and appropriately trained physicians to use a new reagent kit to prepare the radiopharmaceutical technetium-99m labeled albumin colloid. NRC is taking this action because the Food and Drug Administration (FDA) recently approved a "New Drug Application" permitting the interstate distribution of this reagent kit.

EFFECTIVE DATE: June 22, 1983.

FOR FURTHER INFORMATION CONTACT: William J. Walker, Jr., Ph. D., Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 427–4232.

SUPPLEMENTARY INFORMATION: This regulation amends the Nuclear Regulatory Commission's regulation's, "Human Uses of Byproduct Material," 10 CFR Part 35, to add a new reagent kit to NRC's list of authorized radioactive drugs and reagent kits.

As described in NRC's medical policy statement that was published in the Federal Register on February 9, 1979 (44

FR 8242), the NRC relies, for assurance of patient protection, on FDA to approve safety and effectiveness of radioactive drugs. The FDA has recently approved a "New Drug Application" for a reagent kit that is used to prepare the liver, spleen and bone marrow imaging radiopharmaceutical, technetium-99m labeled albumin colloid. Approval of a "New Drug Application" means that FDA finds the drug to be safe and efficacious for the use listed in the product labeling.

The NRC regulations in 10 CFR Part 35 list groups of medical uses of byproduct material that have similar levels of radiation hazard associated with their use. Certain requirements for user training and experience, facilities and equipment, and radiation safety procedures apply to the medical uses of each group. The licensee who is authorized to use the materials in a specific group meets these requirements. The licensee is capable of maintaining radiation safety during the use of the materials in the group and of protecting workers and the public from unnecessary exposure to radiation. As new radiopharmaceuticals are found to be safe and effective by FDA, they are added to the appropriate group in the NRC regulations. Adding this reagent kit to Group III of the NRC's regulations in 10 CFR 35.100 will allow the licensee who is authorized to use other materials listed in Group III to use technetium-99m labeled albumin colloid in patients who, in the physician's judgment, should receive it as the diagnostic agent of choice. Without this addition to the NRC's regulations, even the licensee authorized to use other Group III materials could not use technetium-99m labeled albumin colloid without applying for a license amendment. As a result of this addition to NRC's regulations, patients and physicians will have available to them a new diagnostic radiopharmaceutical without the administrative costs and delays associated with the otherwise necessary amendment of individual licenses.

Due to the minor procedural nature of the amendment, the Commission for good cause finds that the customary notice of proposed rulemaking and public procedure thereon are unnecessary in this case. Supplemental procedures for public reconsideration are provided by the Commission's rules at 10 CFR Part 2, Subpart H, should reconsideration of this rule be necessary. Since the amendment relieves licensees from restrictions under regulations currently in effect, it is effective immediately.

Environmental Impact: Negative Declaration

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in 10 CFR Part 51, that promulgation of this regulation is not a major Federal action significantly affecting the quality of the human environment and therefore an environmental impact statement is not required. The environmental impact appraisal and negative declaration on which this determination is based are available for public inspection at the NRC Public Document Room, 1717 H Street NW., Washington, D.C.

Paperwork Reduction Act Statement

This final rule contains no information collection requirements and therefore is not subject to the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et. seq.).

List of Subjects in 10 CFR Part 35

Byproduct material, Drugs, Health facilities, Health professions, Medical devices, Nuclear materials, Occupational safety and health, Penalty, Radiation protection, Reporting and recordkeeping requirements.

Under the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the following amendment to 10 CFR Part 35 is published as a document subject to codification.

≫48 FR 29677
Published 6/28/83

10 CFR Part 35

Group Licensing for Certain Medical Uses

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: the Nuclear Regulatory Commission (NRC) is amending its regulations to add a device used for instantaneous imaging to its list of devices that may be used by licensed physicians. The hand-held device uses the low energy radiation from an iodine-125 sealed source to produce images of bones or foreign bodies. NRC is adding the device to its list so that physicians, who are adequately trained and licensed to use similar devices, may use the device without having to amend their licenses.

EFFECTIVE DATE: June 28, 1983.

FOR FURTHER INFORMATION CONTACT: Deborah A. Bozik, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone (301) 427-4586.

SUPPLEMENTARY INFORMATION: On March 30, 1983, the Nuclear Regulatory Commission (the Commission) published in the Federal Register (48 FR 13189) a proposed rule to add a medical device to the group of devices listed in §35.100(f) of its regulations (Group IV). Group VI provides for the use of sources and devices containing byproduct material for certain medical activities. The hand-held device uses the low energy radiation from a iodine-125 sealed source of up to 500 millicuries and fiber optics to produce a visible image on a phosphor screen of the extremity of a person being examined. As stated in the March 30 notice, a key reason the Commission selected Group VI of § 35.100(f) is because characteristic of the device resemble the bone mineral analyzer, which also contains an iodine-125 sealed source, and the strontium-90 ophthalmic applicator, which also is portable, both of which are listed in Group VI. The purpose of the rule is to reduce administrative costs by eliminating the need for licensees, already authorized for Group VI, to seek an amendment to their license in order to use the imaging device.

Comments on the Proposed Rule

The public was invited to submit written comments on the proposed rule by April 29, 1983 and 11 comment letters were received. All the commenters supported the rule and raised one of the following topics:

- The suitability of placing the device in Group VI; and
- The extent of physician training and experience needed to safely use the device.

Regarding the suitability of placing the device in Group VI, two commenters pointed out that, except for the bone mineral analyzer, the items in Group VI are used for radiation therapy; while the imaging device is a diagnostic instrument. The commenters suggested that most potential users of the device are not authorized for Group VI and, therefore, would not benefit from the proposed rule. The key reasons the Commission selected Group VI for the imaging device were stated in the March 30, 1983 Federal Register Notice. For example, the same facilities and equipment needed to leak test the sealed source contained in the bone mineral analyzer are needed to leak test the sealed source in the imaging device.

Also, the control and accountability constraints required by individual licenses for the portable Sr-90 ophthalmic applicator are appropriate to control the hand-held imaging device. Two commenters suggested that the Commission create a new medical use group for diagnostic devices. In fact, a revision of Part 35 which contains a provision for a Group VII for diagnostic sealed sources and devices is now under consideration by the Commission. In the interim, the Commission considers Group VI to be the most suitable of the existing medical use groups.

The topic of the extent of physician training and experience needed to safely operate the imaging device was mentioned in seven letters. One commenter suggested that the training and experience requirements for Group VI users would be excessive for physicians wishing to use the imaging device. Several commenters offered their opinion of what constituted adequate training and experience. While physicians already licensed as Group VI users will automatically be qualified to use the imaging device, the Commission will also establish the minimum requirements for physician training and experience to use only the imaging device. The Commission will consider the commenters' suggestions plus the advice of its Advisory Committee on the Medical Users of Isotopes in determining the minimum licensing requirements.

The Commission's Advisory Committee on the Medical Uses of Isotopes was polled regarding the ability of Group VI licensees to use the device safely. Responses were obtained from 10 of the 11 committee members and medical consultants. All responses confirmed that Group VI licensees have adequate training, facilities, and program controls to use the device safely. The poll also contained questions regarding the minimum training and experience needed to use only the device. The Commission will consider the responses to this topic and the suggestions from the publlic comment letters in setting minimum licensing requirements.

As a result of this amendment to the Commission's regulations, patients and physicians will have available to them a new device without the administrative costs and delays associated with the otherwise necessary amendment of individual licenses. Since the rule relieves licensees from restrictions under regulations currently in effect, it is effective immediately.

Environmental Impact: Negative Declaration

The Commission has determined, under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in 10 CFR Part 51, that promulgation of this rule is not a major Federal action significantly affecting the quality of the human environment and that, therefore, an environmental impact statement is not required. The environmental impact appraisal and negative declaration on which this determination is based are available for public inspection at the NRC Public Document Room 1717 H Street NW., Washington, D.C.

Paperwork Reduction Act Statement

This final rule contains no information collection requirements and, therefore, is not subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501, *et seq.*).

Regulatory Analysis

The Commission has prepared a regulatory analysis on this rule. The analysis examines the costs and benefits of the alternatives considered by the Commission. The regulatory analysis is available for inspection in the NRC Public Document Room, 1717 H Street, NW., Washington, D.C. Single copies of the analysis may be obtained from the person indicated under the "FOR FURTHER INFORMATION CONTACT" heading.

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this rule does not have a significant economic impact on a substantial number of small entities. The regulatory analysis prepared in connection with this rule discloses that the approximately 350 Group VI medical licensees may experience some beneficial impact from the rule. The rule will spare each of these licensees, regardless of size, the cost of preparing a license amendment (estimated at about 2 to 5 hours of licensee effort, at an administrative and clerical cost estimated at $335 to prepare the paperwork), the $40 amendment fee, and the delay (length and cost undetermined) associated with the amendment of the license if the licensee decides to use the device.

In the notice of proposed rulemaking, the Commission specifically requested comment on the economic impact of this action on small entities. No comments were received in response to this request.

List of Subjects in 10 CFR Part 35

Byproduct material, Drugs, Health facilities, Health professions, Medical devices, Nuclear materials, Occupational safety and health, Penalty, Radiation protection, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is adopting the following amendments to 10 CFR Part 35.

49 FR 19623
Published 5/9/84
Effective 5/9/84

Information Collection Requirements; Display of OMB Control Numbers

See Part 0 Statements of Consideration

> **49 FR 27923**
Published 7/9/84
Effective 7/9/84

Application Consolidation to NRC Form 313; Application for Material License

See Part 30 Statements of Consideration

PART 39

LICENSES AND RADIATION SAFETY REQUIREMENTS FOR WELL-LOGGING OPERATIONS

PROPOSED RULE MAKING

50 FR 13797
Published 4/8/85
Comment period expires 7/8/85

10 CFR Parts 19, 20, 21, 30, 39, 40, 51, 70, 71, and 150

Licenses and Radiation Safety Requirements for Well-Logging Operations

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission is proposing a regulation that would specify radiation safety requirements for the use of licensed material in well-logging operations. The proposed regulation would provide: (1) Comprehensive and consistent regulations applicable to well-logging operations by consolidating essential radiation safety requirements in a new Part 39, (2) uniform safety requirements in NRC and Agreement States regulations, and (3) safety requirements designed to reduce the risks of accidents involving the rupture of radioactive sources in well-logging operations.

DATE: Submit comments by July 8, 1985. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

ADDRESSES: Submit written comments to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch. Copies of comments received on the proposed rule may be examined at the NRC Public Document Room, 1717 H Street NW., Washington, DC. Single copies of the technical documents referred to in this document may be obtained from Dr. Anthony N. Tse, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555 (301–443–7901).

FOR FURTHER INFORMATION CONTACT: Dr. Anthony N. Tse, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, (301) 443–7901.

SUPPLEMENTARY INFORMATION:

1. Introduction

Uses of Licensed Material in Well-Logging Operations

The oil and gas industry often needs to determine the types and characteristics of the underground formations in a new or existing well. Licensed materials are used to obtain information on certain properties of an underground formation, such as type of rocks, porosity, hydrocarbon content, and density. Licensed materials are also used for similar purposes in coal or mineral exploration.

In well-logging, sealed radioactive sources with associated radiation detectors, known as logging tools, are lowered into a well on a wireline. The depth of the well could range from several hundred feet to greater than 30,000 feet. Information collected by the detectors is sent to the surface through the wireline and plotted on a chart as the logging tool is slowly raised from the bottom of the well. Americium-241 (typically 0.25 curie to 20 curies) and cesium-137 (typically 2 to 3 curies) are the radioactive materials most frequently used for this purpose.

In subsurface tracer studies, a small amount of radioactive material in liquid or gaseous form is used. After the liquid of gas tracer is injected into the well, a detector is used in the well to monitor the dispersion of the tracer material. This information will help determine certain underground characteristics such as fluid flow rate and the channeling effect. Iodine-131 (typically 5 to 20 millicuries) is the material most frequently used in subsurface tracer studies.

Other licensed materials used in well-logging operations include cobalt-60 used in collar markers, radioactive iron used in nails, depleted uranium used in sinker bars, and iridium-192 used in sands. Collar markers use Co-60 wire (about 1 to 5 microcuries) to mark collars between two sections of casing and provide positive depth measurement. Radioactive iron nails are used to indicate locations of perforations. Sinker bars are constructed of solid depleted uranium (usually weighing 50 to 100 pounds) and are used to provide additional weight to help push a light weight logging tool through the drilling fluid, called mud by the drilling industry, down to the bottom of the well. Sands mixed with small amount of iridium-192 are used to determine the extent of underground hydraulic fracturing.

NRC and Agreement States' Roles

Twenty-seven Agreement States, including most major oil producing States, have assumed responsibility for regulating certain activities, including the use of radioactive materials in well-logging operations, by agreements with the NRC. Each Agreement State issues licenses to persons who use radioactive material in well-logging operations in the State.

The NRC issues licenses to persons using radioactive materials in well-logging operations in non-Agreement States. These licenses specify the radiation safety requirements applicable to well-logging operations that the licensee must follow. The NRC has, as of November 1984, 173 licensees authorized to use radioactive materials in well-logging operations. The Agreement States have approximately 400 licensees involved in well-logging operations.

Well-logging licensees from one State frequently perform well-logging jobs in other States. To avoid duplication of licensing effort, NRC permits, under reciprocity, Agreement States licensees to operate in non-Agreement States according to the conditions of the license issued by their home State. Reciprocity also applies to licensees of the NRC that wish to operate in Agreement States as well as between the different Agreement States. Therefore, compatibility between NRC regulations and Agreement State regulations is essential to permit licensees to conduct well-logging operations in various States while maintaining a consistent and effective level of protection necessary to ensure public health and safety.

NRC's Current Regulatory Practices

Except for requirements concerning the abandonment of irretrievable well-logging sources set forth in 10 CFR 30.56 and 70.60, current NRC regulations, do not provide radiation safety requirements specific to the use of licensed material in well-logging operations. General safety requirements, however, are contained in 10 CFR Parts

20, 30, 40, and 70. At present, NRC reviews a licensee's specific safety program as part of the license application, and incorporates the safety program into the license as license conditions.

Problems with the Current Practice

A major problem with the current practice is that radiation safety requirements applicable to the industry are specified as license conditions on a case-by-case basis rather than spelled out in uniform regulations that are applicable to all licensees. This requires duplication of effort and allows for discrepancies in requirements among specific licenses issued by NRC and the Agreement States. Problems in the consistent and uniform application of these requirements could become a greater concern because, under the NRC's program for the decentralization of material licensing actions, well-logging licenses are issued by the five NRC Regional Offices instead of NRC Headquarters.

Though there are about 50,000 well-logging operations each year, the probability of an accident is small. Nonetheless, accidents have occurred and additional safety requirements are needed to reduce even further the risk of an accident.

There were five incidents which occurred between August 1982 and September 1983 involving radioactive sources used in well-logging operations. Three incidents involved the reputure of sources in uncontrolled workshop environments by workers performing machining or drilling operations. Two incidents involved the rupture of sources in well holes during logging-tool recovery operations. The cost associated with the Cleanup of radioactive contamination from these incidents is estimated to be in excess of $1.5 million

Actions taken by Agreement States

Recognizing the need for comprehensive and consistent radiation safety standards, the Conference of Radiation Control Program Directors established a task force in 1974 to develop necessary standards for well-logging operations. The task force was composed of representatives from States, industry, and Federal agencies, including NRC. By 1981, a set of model regulations was proposed to the Conference by the task force. In keeping with previous practices of the organization, the Conference adopted the well-logging requirements as Part W of the "Suggested State Regulations for Control of Radiation." Four Agreement States (Arkansas, Kentucky, Oregon, and Texas) have already adopted Part W requirements as State regulations without significant changes. Several other Agreement States are considering adopting Part W requirements.

NRC's Proposed Approach

The NRC is proposing to amend its regulations to include specific radiation safety requirements for well-logging operations. These requirements are included in the proposed 10 CFR Part 39, a new part exclusively dedicated to well-logging operations.

The proposed rule is needed for the following reasons:

(1) The proposed rule would provide comprehensive and consistent regulations applicable to well-logging operations. Current NRC regulations do not provide specific requirements. Specific requirements pertaining to well-logging operations are imposed as licensing conditions.

(2) The proposed rule would incorporate requirements similar to Part W of the Suggested State Regulations. Four Agreement States have adopted Part W as State regulations and others are considering its adoption. Consistency between NRC and Agreement State regulations is essential for well-logging operations because many companies operate in both Agreement and Non-Agreement States.

(3) The proposed rule includes safety requirements designed to reduce the risks of accidents involving the rupture of radioactive sources and the spread of radioactive contamination. These incidents may result from operations conducted to remove a stuck source from a well-logging device or to retrieve a well-logging device lodged in a well.

(4) The proposed rule also includes safety requirements involving the use of radioactive collar markers, uranium sinker bars, and of a sealed source in a well without surface casing.

If these requirements are adopted as final regulations, NRC would encourage the Conference of Radiation Control Program Directors and the Agreement States to adopt similar requirements in order to achieve compatible regulations.

A new part (10 CFR Part 39), dedicated exclusively to well-logging operations, is proposed to specify the various safety requirements. The proposed new part parallels the existing Part 34 which is dedicated exclusively to radiographic operations. A new part is needed because these operations use byproduct material, source material, and special nuclear material. If these safety requirements were not included in one part, they would have to be repeated in Parts 30 (byproduct material), 40 (source material) and 70 (special nuclear material). For instance, the existing regulation on irretrievable well-logging sources is repeated in Parts 30 and 70 for sources containing byproduct material and special nuclear material, respectively. Furthermore, if the safety requirements were fragmented throughout Parts 30, 40, and 70, licensees, NRC licensing reviewers, and NRC inspectors could have difficulty in determining the regulations applicable to a specific situation.

2. Discussion of the Proposed Rule

The proposed Part 39 would prescribe specific safety requirements for well-logging operations that use licensed materials. General provisions in Parts 30, 40 and 70, such as renewal, amendment or termination of licenses, would also be applicable to well-logging licensees. The following sections provide a discussion of the major provisions of the proposed Part 39.

A. Agreement With Well Owner or Operator

The proposed rule (§ 39.15) would require that a license (a well-logging company) enter into a written agreement with a well owner or operator, whichever engaged the licensee to perform the well-logging operations, before the licensee could use sealed sources in well-logging. The requirement to enter into a written agreement on abandonment procedures for irretrievable well-logging sources was published as a final rule in the **Federal Register** (10 CFR 30.56, 70.60, and 150.20) on August 29, 1983 (48 FR 39036). The proposed Part 39 has incorporated the existing requirement for an agreement and proposes to remove §§ 30.56 and 70.60 and to modify § 150.20.

The proposed rule specifies the terms of this agreement. The well owner or operator would agree, if a sealed source is lodged in the well, to: (1) Make a reasonable effort to recover the sealed source; (2) not permit specific types of recovery operations that could endanger the integrity of the sealed source; (3) not release contaminated equipment or areas, such as areas surrounding the well, for unrestricted use unless the equipment or the area has been decontaminated (Guidance on release of equipment or areas for unrestricted use is available on a case-by-case basis from the NRC staff. In general, limits for equipment are similar to those in Regulatory Guide 1.86, "Termination of Operating Licenses for Nuclear Reactors."); and (4) implement specified abandonment procedures when a sealed source is deemed irretrievable. The sealed source lodged in the well must be retrieved or properly abandoned to avoid possible source rupture by subsequent re-entry into the well.

This requirement is needed because the licensee (the well-logging company) may not have the legal authority or resources to recover a tool and its sealed source if it becomes lost in a well. The well owner or operator controls the activities at the well. When a tool containing sealed source is lost in the well, the well owner or operator could engage a "fishing company" to recover it. The fishing company is usually responsible directly to the well owner or operator. The licensed well-logging company has no legal right to direct or control the activity of the fishing compay. Therefore, the contractual agreement between the licensee and the well owner or operator is necessary to obligate the well owner or operator to (1) recover the sealed source in a safe manner, (2) properly abandon an irretrievable source, and (3) prevent release of contaminated equipment or areas until they have been decontaminated.

It should be noted that the NRC is making the licensee responsible for the sealed source during well-logging until the sealed source is removed from the temporary jobsite or the completion of the abandonment procedures, if the source is determined to be irretrievable. Thus, NRC is making the licensee responsible for ensuring compliance with the regulations or for pursuing every legal avenue, based on the written agreement, to achieve compliance. The written agreement could assign to the well owner or operator, under the supervision of the licensee in areas of radiation safety, the responsibility for carrying out the recovery operations or abandonment procedures. However, the written agreement could not transfer the possession of the sealed source from one pary to another without specific NRC approval.

The Commission considered another approach to allocate responsibility among the various parties involved in the well-logging operations. It would have provided a general license to the well owner or operator, whichever engaged the well-logging company. Under this approach, NRC would have imposed the same safety requirements as would be contained in the written agreement directly on the party that had the authority to fulfill these requirements. This alternative was not pursued for the following reasons:

(1) Current industry practice, of having written agreements between licensees and well owners or operators, has worked satisfactorily for the last 20 years;

(2) The well-logging company is in a better position to handle radiological problems than the well owner or operator, unless the latter's personnel are also properly trained, which would be duplicative and costly;

(3) Licensing well owners or operators as well as well-loggers may create confusion about who is responsible for radiological safety when the sealed source enters or leaves the well.

The Commission is interested in comments on the costs, advantages, and disavantages of the proposed approach and on the alternative.

B. Radiation Detection Instruments

The proposed rule (§ 39.33(a)) would require that a licensee have a radiation survey instrument at each field station and at each temporary jobsite. These survey instruments are needed to perform routine radiation surveys and to measure for any potential radioactive contamination. Each survey instrument would have to be capable of measuring 0.1 milliroentgen per hour through at least 100 milliroentgens per hour. The requirement of 100 milliroentgens per hour is proposed because a licensee occasionally needs to define the boundaries of a high radiation area as required by 10 CFR 20.203(c)(2). A grandfather clause (for a period of 5 years) is provided for existing survey instruments capable of measuring 0.1 milliroentgen per hour through at least 20 milliroentgens per hour to reduce the economic impact on licensees. A 5-year period is proposed because the average life of a field-use survey intrument is estimated to be 5 years.

Although the required radiation survey instruments are adequate for routine radiation surveys, they are not designed to handle unlikely events such as the rupture of a sealed source resulting in low-level contamination of americium–241 in the drilling fluid or mud. Therefore, the proposed rule would also require that a licensee have available, when needed, radiation detection instruments (for example, a high range survey meter or a sodium iodide crystal detector) that are capable of measuring radiation levels or contamination levels which could be encountered during an acccident. For example, before the initiation of recovery of an americium–241 source from a well, the licensee would have to have an instrument present at the jobsite that is sensitive enough to detect americium–241 contamination. Other types of accidents could also result in high radiation levels; thus, a high range survey meter may be needed. The licensee could own the instrument or use a consulting service that has such an instrument.

A 6-month calibration interval would be specified for each survey instrument. This interval is adequate, based on licensing experience, to ensure the proper operation of the instrument and is consistent with practices presently required in well-logging licenses.

C. Leak Testing of Sealed Sources

The proposed rule (§ 39.35) would require that sealed sources be leak tested at least every 6 months. Because these sources are subjected to rough handling and servere environmental conditions in a well, it is necessary that they maintain their integrity. A leaking sealed source, if undetected, could cause extensive radioactive contamination to the well, equipment, personnel, environment. The leak test requirement is consistent with the current requirement for well-loggers and many other types licensees.

Several exemptions are provided in the proposed rule to reduce the burden of leak testing on the industry. The sealed sources exempted from leak testing requirements are those that would present essentially no hazard to the public or the environment in the event of a leak because they contain either gaseous, short lived, or small quantities of radioactive materials.

D. Physical Inventory

The proposed rule (§ 39.37) would require that a semi-annual physical inventory be made to account for sources of licensed material. This requirement is needed because the source used in well-logging operations are frequently transported to and from temporary jobsites. An accurate account of each of the sources would ensure that no source has been lost. The 6-month period is proposed because a licensee could conduct a physical inventory and leak testing at the same time, thus, reducing its burdens.

E. Design and Performance Criteria for Sealed Sources

Design and performance criteria are proposed in § 39.41(a) for all sealed sources except those containing gaseous licensed material. These have been proposed as minimum requirements, and are the same (except for the pressure test) as the requirements for well-logging sources in industry standard ANSI N542, "Sealed Radioactive Sources, Classification," published by the National Bureau of Standards (NBS Handbook 126) in 1978.

However, sealed sources used in well-logging are subject to more severe environmental conditions, such as high pressure and high temperature. Therefore, several additional requirements are proposed to provide further assurances that, under accident conditions, the source is unlikely to lose its integrity. These requirements would specify that each individual sealed source would have to (1) pass a pressure test; (2) be doubly encapsulated; and (3) contain licensed material in chemical and physical forms which are as insoluble and nondispersible as practical (for example, cesium chloride would not satisfy this requirement because it is soluble in water). A single encapsulated source has a greater change of causing radioactive contamination than a doubly encapsulated source, and soluble or dispersible material from a ruptured source could cause more radioactive contamination than less soluble, less dispersible material. These requirements would (1) phase out the use of substandard sources in well-logging, (2) result in lower probability of source rupture in the well, and (3) mitigate the consequence of contamination in the event of a rupture.

The proposed rule would require that a license not use a new sealed source manufactured after [1 year after the effective date of the final rule] unless it is designed and manufactured in accordance with proposed § 39.41(a). The 1-year grace period is proposed to provide sealed source manufacturers sufficient time to produce sources complying with NRC's requirements.

Sealed sources manufactured before [1 year after the effective date of the final rule] could be used by a licensee until [2 years after the effective date of the final rule]. After this 2-year period, however, these sources could no longer be used unless they were certified, by the manufacturer or other testing organization, as having satisfied the requirements specified in § 39.41(b).

Any source that could not meet the performance criteria proposed in § 39.41(b) would have to be phased out of well-logging. Most sealed sources manufactured after 1978 have complied with the ANSI Standard and there should not be a problem in their ability to comply with the requirements specified in § 39.41(b).

F. Inspection, Maintenance, and Opening of Source or Source Holder

The proposed rule (§ 39.43(a)) would require that each licensee inspect equipment and tools for obvious defects before the equipment is used each day. Furthermore, paragraph (b) would require that each licensee inspect and maintain equipment and tools at intervals not to exceed 6 months. The licensee would be required to check the equipment and tools for label legibility and for the absence of physical damage. If any equipment or tools critical to radiation safety were found to be worn or damaged, paragraph (c) would require that the licensee remove them from service until repairs were made.

Paragraph (d) of this section would prohibit the licensee from performing maintenance on a sealed source or a source holder containing a source, unless the licensee has a written instruction approved by NRC. This maintenance may include changing the O-ring on the source holder containing a source or changing the sealed source from one source holder to another source holder. This requirement is needed because the worker is very close to the sealed source during this maintenance, and thus, could receive a significant radiation dose.

This section would also prohibit a licensee from forcing a stuck sealed source out of the source holder or out of the logging tool by operations that could endanger its integrity unless specifically authorized by the NRC. Prohibited operations could include, but would not be limited to: drilling, cuttng, or chiseling. These operations would be prohibited because they could accidently rupture the sealed source and could cause radioactive contamination of the facility, personnel and environment. For similar reasons, a licensee would be prohibited from repairing, opening, or modifying a sealed source unless specifically authorized by NRC to perform these operations.

G. Subsurface Tracer Studies

Radioactive materials in liquid or gaseous forms and other materials, such as sand labeled with radionuclides, are used as tracer materials in subsurface tracer studies. These materials could accidently spill on clothing, contaminate hands, be ingested, or, in the case of gaseous or volatile material, be inhaled by personnel. The proposed rule (§ 39.45) would require that protective gloves, clothing, and other equipment be used by individuals who handle tracer materials. When volatile materials such as iodine are handled by employees of licensees who have bioassay requirements incorporated in their licenses in accordance with § 20.108, a bioassay could be required when those employees work in field operations with more than 50 millicuries of I–125 or I–131. A licensee would also be required to maintain the temporary jobsite and the field station free from contamination from licensed materials.

In addition, a licensee would not be allowed to inject any licensed material into a fresh water aquifer as part of a subsurface tracer study unless specifically authorized to do so by the Commission, because the water could be used for human or animal consumption or to irrigate crops.

H. Radioactive Markers

The proposed rule (§ 39.47) would prohibit the use of radioactive markers (used for determining the depth of a well), unless the radioactivity of each marker, at the time of installation, is less than the quantity specified in § 30.71, Schedule B. This limitation in the amount of radioactivity is necessary because it is impracticable for the licensee that installs the radioactive marker to recover the marker when the well owner or operator removes the well casings from the well at a later date.

I. Uranium Sinker Bars

The proposed rule (§ 39.49) would require that after [one year from effective data of the final rule] each uranium sinker bar (used as a weight to pull a logging tool toward the bottom of a well) bear a legend: "CAUTION–RADIOACTIVE–DEPLETED URANIUM" and "NOTIFY CIVIL AUTHORITIES (or COMPANY NAME) IF FOUND." This requirement is needed to ensure that, if a uranium sinker bar is lost, someone who finds the bar could identify it as radioactive and would return it to the company. (Because uranium is source material, the licensee must also comply, as necessary, with requirements in 10 CFR Part 40, "Domestic Licensing of Source Materials.")

J. Use of Sealed Source in a Well Without Surface Casing

The proposed rule (§ 39.51) would prohibit the use of a sealed source in a well without surface casing unless procedures for protecting fresh water aquifer zones are specifically approved by NRC. (A surface casing is a pipe or tube used as lining in the well to isolate the fresh water zone from the well). The purpose of this requirement is to minimize the possibility of contamination of fresh water aquifer zones by accidental rupture of a sealed source. In general, most wells have surface casings to prevent oil or other particulates from entering these zones. However, if surface casings cannot be placed, a licensee may not use a sealed source in an uncased well, ulese NRC has specifically approved the licensee's procedures for providing adequate protection of the fresh water aquifer from radioactive contamination.

Because most uncased wells are primarily encountered in mineral logging, licensees performing mineral logging operations may want to provide specific comments on this requirement, especially on the feasiblity of protective alternatives.

K. Training

Although general requirements on instruction and training are specified in 10 CFR 19.12 and 30.33(a)(3), the proposed rule (§ 39.61) would establish specific training requirements for logging supervisors and logging assistants. Licensees would be prohibited from permitting an individual to perform well-logging operations unless the individual has been properly trained in accordance with the requirements specified in this section. Training is needed to provide radiation workers with sufficient knowledge and practical experience on radiation safety to ensure safe use of licensed materials. The level of knowledge they would need would depend, of course, on their responsibilities.

For logging supervisors, the proposed rule would require, at a minimum, 40 hours of formal classroom training in the subjects listed under § 39.61(e). Furthermore, it would require that an individual must have, at a minimum, 3 months of on-the-job training. This requirement is needed to ensure that a logging supervisor has sufficient practical experience on radiation safety procedures to handle routine operations and unanticipated emergencies in a safe manner.

Because logging assistants work under the personal supervision of a logging supervisor, their training requirements can be less stringent than those for the logging supervisors. The proposed rule would require that an assistant be instructed on applicable sections of Parts 19, 20, and 21, and on the licensee's operating and emergency procedures. It would also require that the individual be able to use remote tools, survey instruments, etc., to perform work properly under the supervision of the logging supervisor.

The proposed rule would also require that logging supervisors and logging assistants be retrained annually after their initial training. This periodic retraining is needed to: (1) Refresh their understanding of basic radiation safety practices, (2) instruct them on any new procedures or on the use of new radiation detection instruments and new tools, and (3) review regulatory requirements or new regulations which may affect their work.

L. Operating and Emergency Procedures

The proposed rule (§ 39.63) would require that each licensee develop and follow written procedures for well-logging operations and for dealing with emergencies. These written procedures would also be used as: (1) training materials for instructing logging supervisors and logging assistants, (2) reference materials at a field station and at a temporary jobsite, and (3) supporting documents in licensing applications.

M. Personnel Monitoring and Radiation Surveys

The proposed rule (§ 39.65) would require that logging supervisors and logging assistants wear personnel monitoring equipment at all times during the well-logging operation. The requirements in § 39.65 (a), (b), and (c) are specific applications of the existing broader requirements in §§ 20.108, 20.202, and 20.401, respectively. These requirements are repeated in this part because they constitute key features of a radiation protection program.

Similarly, the proposed rule (§ 39.67) would also require that the licensee conduct radiation surveys. This requirement is a specific application of the existing broader requirement in § 20.201, "Surveys." Instead of the 2 years retention for survey records as specified in § 20.401, a 3-year retention period is proposed because the NRC inspection period is every 3 years for well-logging licensees.

If gaseous or volatile tracer materials are used, the licensee may be required to provide bioassay service to individuals handling the tracer materials (§ 39.65(b)). Whether a bioassay is needed depends on the type of radioactive materials and quantity used. For example, Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131," states that bioassays should be performed when individuals work in field operations with more than 50 millicuries of I-125 or I-131.

N. Contamination Control

The proposed rule (§ 39.69) would require that licensees monitor for radioactive contamination during fishing or source recovery operations, initiate emergency procedures if a sealed source ruptures, and decontaminate any equipment, personnel, or environment that is contaminated. This requirement is needed to assure that any rupture of a sealed source in a well during a fishing operation is detected and reported and that emergency procedures are initiated. Also, paragraph (c) would require that the licensee decontaminate any contaminated equipment, areas, or personnel. Guidance on release of equipment or areas for unrestricted use is available case-by-case from the NRC. In general, limits similar to those in Regulatory Guide 1.86 should be met. The licensee may perform the decontamination or use a contracting or consulting service to perform it. These requirements are important to avoid the possibility of unnecessary wide-spread contamination if a sealed source is ruptured. The monitoring would detect contamination from a source rupture and the initiation of emergency procedures would limit the spread of contamination. Furthermore, decontamination would prevent contaminated objects from leaving the site and thus further prevent wide-spread contamination to public areas.

O. Security

The proposed rule (§ 39.71) would require that the licensee maintain surveillance and control of the jobsite's restricted areas (as defined in Part 20) and prevent unauthorized personnel, such as employees of an oil company or drilling company, from entering a restricted area. This requirement is needed to avoid the inadvertent exposure of these personnel to radiation.

P. Documents and Records Required at Field Stations and Temporary Jobsites

The proposed rule (§§ 39.73 and 39.75) would require that certain documents and records be kept at a field station or a temporary jobsite. These records are needed so that operating personnel can have easy access to the documents they need to perform the job, to follow any operational restrictions, or to use emergency procedures if an accident occurs. Records of radiation surveys, instrument calibrations, sealed source leak tests, etc., are needed for the licensee to make safety checks or to check schedules for maintenance. The recordkeeping requirement would also enable NRC inspectors to determine whether the requirements have been met.

Q. Notification of Incidents and Lost Sources and Abandonment Procedures for Irretrievable Sources

The proposed rule (§ 39.77(a)) would require, in addition to general reporting requirements in Part 20, immediate notification if (1) licensed material has been lost in or near freshwater aquifers or (2) a sealed source has been ruptured at the licensee's facility or temporary jobsite. This requirement is needed because these conditions could cause radioactive contamination.

Paragraph (b) would also require that the licensee notify NRC of incidents and lost sources. (This does not include loss of a sealed source lodged in a well because it is covered by paragraph (c) of this section.) The requirements are presently contained in a more general form in §§ 20.402, 20.403, and 20.405 and are repeated in specific form for the sake of completeness.

Paragraphs (c) and (d) consolidate the existing regulations, 10 CFR 30.56 and 70.60, on irretrievable well-logging sources into one section in Part 39. The consolidation would be beneficial because it would put all requirements for well-logging operations in a single part. The proposed text is essentially the same as the existing text under §§ 30.56 and 70.60, which would be deleted.

R. Application for Exemption

The proposed rule (§ 39.91) would permit a licensee to apply for an exemption from the requirements in this part. This section is needed to allow NRC to judge on a case-by-case basis whether certain requirements can be waived if it determines that the exemption will not result in undue hazard to life or property.

3. Summary

The Commission believes that the proposed rule, if adopted, would provide a comprehensive and consistent set of regulations that would help maintain compatibility between NRC's and Agreement States' regulations. Furthermore, the proposed rule would also establish additional requirements that would reduce the potential for and severity of an accident. The Commission also believes that the economic impact of the rule would be small. The economic impact is analyzed in detail in a draft regulatory analysis prepared on this proposed rule.

Interested persons are encouraged to comment on the proposed rule, on its impact on the public and the industry, and on the draft regulatory analysis.

Finding of No Significant Environmental Impact: Availability

The Commission has detemined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that this rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment and therefore an environmental impact statement is not required. This rule would not significantly affect the quality of the human environment because the proposed requirements are designed to control the use of licensed materials in well-logging operations. On the other hand, these requirements, if adopted, would reduce occupational radiation exposures and would also reduce the chances for and consequences of accidents involving licensed materials. Furthermore, most of these requirements are already being complied with by licensees as licensing conditions. Therefore, the proposed rule would have no measurable negative environmental impact. The environmental assessment and finding of no significant impact on which this determination is based are available for inspection at the NRC Public Document Room, 1717 H Street NW., Washington, DC. Single copies of the environmental assessment and finding of no significant impact are available from Dr. Anthony N. Tse, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555 (301–443–7901).

Paperwork Reduction Act Statement

This proposed rule contains new information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). It has been submitted to the Office of Management and Budget for reveiw and approval of the paperwork requirements.

Regulatory Analysis

The Commission has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. The draft analysis is available for inspection in the NRC Public Document Room, 1717 H Street NW., Washington, D.C. Single copies of the analysis may be obtained from Dr. Anthony N. Tse, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555 (301–443–7901).

The Commission requests public comment on the draft analysis. Comments on the draft analysis may be submitted to the NRC as indicated under the ADDRESSES heading.

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certified that this rule, if adopted, will not have a significant economic impact upon a substantial number of small entities. The proposed rule would provide radiation safety requirements, uniformity in the NRC and Agreement States regulations, and requirements that would reduce the risks of accidents involving radiation or radioactive materials. The proposed rule affects about 173 specific licensees of which approximately 60% are small entities based on the size standards of the Small Business Administration set out in 13 CFR Part 121 (February 9, 1984, 49 FR 5024). These licenses are issued to companies performing well-logging operations.

The Commission estimates that the total cost of compliance with the requirements contained in this proposed regulation would be approximately $7,400 a year for an average well-logging licensee. However, many well-logging licensees are already complying with most of these requirements because the requirements are currently imposed as conditions of the license under which they operate. Therefore, the acutal increases in the compliance cost to most licensees would be considerably smaller. The cost to an average well-logging licensee for those requirements not already imposed under a license condition would be approximately $2,000 a year.

The Commission does not believe that this regulation would impose a significant economic impact on most licensees. A detailed analysis of the cost of each individual requirement imposed by the regulation appears in the Regulatory Analysis prepared for this action. The Commission is particularly interested in receiving comment from well-logging licensees on the cost estimates contained in the Regulatory Analysis and on the assumptions on which these estimates are based. The Commission is also interested in receiving comment from small licensees about the potential impact of the proposed regulation and the resultant cost of these requirements on their operations.

Any small entity subject to this regulation which determines that, because of its size, it is likely to bear a disproportionate adverse economic impact should notify the Commission of this in a comment that indicates the following:

(a) The licensee's size in terms of annual income or revenue, number of employees, number of well-logging trucks, and average number of wells logged or serviced annually;

(b) How the proposed regulations would result in a significant economic burden upon the licensee as compared to that on a larger licensee; and

(c) How the proposed regulations could be modified to take into account the licensee's differing needs or capabilities.

List of Subjects

10 CFR Part 19

Environmental protection, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Penalty, Radiation protection, Reporting and recordkeeping requirements, Sex discriminination.

10 CFR Part 20

Byproduct material, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Penalty, Radiation protection, Reporting and recordkeeping requirements, Special nuclear material, Source material, Waste treatment and disposal.

10 CFR Part 21

Nuclear power plants and reactors, Penalty, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 30

Byproduct material, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Penalty, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 39

Byproduct material, Nuclear material, Oil and gas exploration—well logging, Penalty, Reporting and recordkeeping requirements, Scientific equipment, Security measures, Source material, Special nuclear material.

10 CFR Part 40

Government contracts, Hazardous materials—transportation, Nuclear materials, Penalty, Reporting and recordkeeping requirements, Source material, Uranium.

10 CFR Part 51

Administrative practice and procedure, Environmental impact statement, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements.

10 CFR Part 70

Hazardous mateirials—transportation, Nuclear materials, Packaging and containers, Penalty, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Security measures, Special nuclear material.

10 CFR Part 71

Hazardous materials—transportation, Nuclear materials, Packaging and containers, Penalty, Reporting and recordkeeping requirements.

10 CFR Part 150

Hazardous materials—transportation, Intergovernmental relations, Nuclear materials, Penalty, Reporting and recordkeeping requirements, Security measures, Source material, Special nuclear material.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is proposing to adopt 10 CFR Part 39.

It is proposed to amend 10 CFR as follows:

1. Part 39 is added to 10 CFR Chapter I to read as follows:

PART 39—LICENSES AND RADIATION SAFETY REQUIREMENTS FOR WELL-LOGGING OPERATIONS

Subpart A—General Provisions

Sec.
39.1 Purpose and scope.
39.2 Definitions.
39.5 Interpretations.
39.8 Information collection requirements: OMB approval.

Subpart B—Specific Licensing Requirements

39.11 Application for a specific license
39.13 Specific licenses for well-logging operations.
39.15 Requirement for an agreement with well owner or operator.
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39.31 Labels, security and transportation precautions.
39.33 Radiation detection instruments
39.35 Leak testing of sealed sources.
39.37 Physical inventory.
39.39 Utilization records.
39.41 Design and performance criteria for sealed sources.
39.43 Inspection, maintenance, and opening of a source or source holder.
39.45 Subsurface tracer studies.
39.47 Radioactive markers.
39.49 Uranium sinker bars.
39.51 Use of a sealed source in a well without surface casing.

Subpart D—Radiation Safety Requirements

39.61 Training.
39.63 Operating and emergency procedures.
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39.67 Radiation surveys.
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Subpart E—Security, Records, Notifications

39.71 Security.
39.73 Documents and records required at field stations.
39.75 Documents and records required at temporary jobsites.
39.77 Notification of incidents and lost sources; abandonment procedures for irretrievable sources.

Subpart F—Exemptions

Sec.
39.91 Applications for exemptions.

Subpart G—Enforcement

39.101 Violations.

Authority: Sections 53, 57, 62, 63, 65, 69, 81, 82, 161, 182, 183, 186, 68 Stat. 929, 930, 932, 933, 934, 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2092, 2093, 2095, 2099, 2111, 2112, 2201, 2232, 2236, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

For purposes of sec. 223, 68 Stat. 958 as amended (42 U.S.C. 2273): §§ 39.15, 39.31–39.51, 39.61–39.77 are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§ 39.15, 39.33–39.43, 39.61–39.67, 39.73–39.77 are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

Subpart A—General Provisions

§ 39.1 Purpose and scope.

(a) This part prescribes requirements for the issuance of a license authorizing the use of licensed materials including sealed sources, radioactive tracers, radioactive markers, and uranium sinker bars in well-logging operations in a single well. This part also prescribes radiation safety requirements for persons using licensed materials in these operations. The provisions and requirements of this part are in addition to, and not in substitution for, other requirments of this chapter. In particular, the provisions of Parts 19, 20, 21, 30, 40, 70, 71, and 150 of this chapter apply to applicants and licensees subject to this part.

(b) The requirements set out in this part do not apply to the issuance of a license authorizing the use of licensed material in tracer studies involving multiple wells, e.g., field flooding studies.

§ 39.2 Definitions.

"Casing" means a metal pipe or tube used as a lining for oil or gas wells to prevent collapse of the well-bore.

"Field station" means a facility where licensed material may be stored or used and from which equipment is dispatched to temporary jobsites.

"Fresh water aquifer," for the purpose of this part, means a geological formation that is capable of yielding a significant amount of fresh water to a well or spring.

"Injection tool" means a device used for controlled subsurface injection of radioactive tracer material.

"Irretrievable well-logging source" means any sealed source containing licensed material that is pulled off or not connected to the wireline that suspends the source in the well and for which all reasonable effort at recovery has been expended.

"Licensed material" means byproduct material, source material, or special nuclear material received, possessed, used, or transferred under a license issued by the Commission under the regulations in this chapter.

"Logging assistant" means an individual who assists the logging supervisor in performing the well-logging operations.

"Logging supervisor" means an individual who provides personal supervision of the use of licensed material at the temporary jobsite and who is responsible to the licensee for assuring compliance with the requirements of the Commission's regulations and the conditions of the license.

"Logging tool" means a device used subsurface to perform well-logging.

"Mineral logging" means any logging performed for the purpose of mineral exploration other than oil or gas.

"Personal supervision" means guidance and instruction by a logging supervisor who is physically present at the temporary jobsite and in such proximity that personal contact with the logging assistants is maintained and that immediate assistance can be given.

"Radioactive marker" means licensed material used for the purpose of depth determination or direction orientation. This term includes radioactive collar markers and radioactive iron nails.

"Sealed source" means any licensed material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

"Source holder" means a housing or assembly into which a sealed source is placed for the purpose of facilitating the handling and use of the source in well-logging operations.

"Subsurface tracer study" means, for the purpose of this part, the release of unsealed license material or a substance labeled with licensed material in a single well for the purpose of tracing the movement or position of the material or substance in the well-bore or adjacent formation (this term does not include the use of licensed material in field flooding studies).

"Surface casing" means a pipe or tube used as a lining in a well to isolate the fresh water zone from the well.

"Temporary jobsite" means a place to which licensed materials are dispatched to perform well-logging operations or subsurface tracer studies.

"Uranium sinker bar," for the purpose of this part, means a weight containing depleted uranium used for the purpose of providing additional force to pull a logging tool down toward the bottom of a well.

"Well-bore" means a drilled hole in which well-logging operations and subsurface tracer studies are performed.

"Well-logging" or "wireline service operation," for the purpose of this part, means the lowering and raising of measuring devices or tools which contain licensed material into well-bores or cavities for the purpose of obtaining information about the well or adjacent formations which may be used in oil, gas, mineral, or geological exploration.

"Well-logging operation" means any activity involving licensed material performed in a well, including well-logging, mineral logging, subsurface tracer studies, use of radioactive markets, radioactive iron nails, uranium sinker bars, and radioactive sands.

"Wireline" means a cable containing one or more electrical conductors which is used to lower and raise logging tools in the well-bore.

§ 39.5 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

§ 39.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.. 3501 et seq.). OMB has approved the information collection requirements contained in this part under control number 3150–____.

(b) The approved information collection requirements contained in this part appear in §§ 39.11, 39.13, 39.15, 39.31, 39.33, 39.35, 39.37, 39.39, 39.41, 39.43, 39.49, 39.61, 39.65, 39.67, 39.73, 39.75, and 39.77.

Subpart B—Specific Licensing Requirements

§ 39.11 Application for a specific license.

A person, as defined in § 30.4(k) of this chapter, shall file an application for a specific license authorizing the use of licensed material in well-logging operations on Form NRC 313, "Application for Material License." Each application for a license, other than a license exempted from Part 170 of this chapter, must be accompanied by the fee prescribed in § 170.31 of this chapter. The application must be sent to the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter.

§ 39.13 Specific licenses for well-logging operations.

The Commission will approve an application for a specific license for the use of licensed material in well-logging operations if the applicant meets the following requirements:

(a) The applicant shall satisfy the general requirements specified in § 30.33 of this chapter for byproduct material, in § 40.32 of this chapter for source material and in § 70.33 of this chapter for special nuclear material, as appropriate, and any special requirements contained in this part.

(b) The applicant shall develop a program for training logging supervisors and logging assistants and submit to the Commission a schedule or description of this program which specifies the—

(1) Initial training;

(2) Annual retraining;

(3) On-the-job training;

(4) Means the applicant will use, including a copy of the written test, to demonstrate the logging supervisor's knowledge and understanding of and ability to comply with the Commission's regulations and licensing requirements, and the applicant's operating and emergency procedures; and

(5) Means the applicant will use, including a copy of the written test or an outline of the oral test, to demonstrate the logging assistant's knowledge and understanding of and ability to comply with, the applicant's operating and emergency procedures.

(c) The applicant shall establish and submit to the Commission written operating and emergency procedures as described in § 39.63.

(d) The applicant shall establish and submit to the Commission a program for annual internal inspections of the performance of each logging supervisor and assistant to ensure that the Commission's regulations, license requirements, and the applicant's operating and emergency procedures are followed by these personnel. Inspection records must be retained for 3 years after each annual internal inspection.

(e) The applicant shall submit a description of its overall organizational structure pertaining to the well-logging operations, including specified delegations of authority and responsibility.

(f) (1) If the applicant wants to conduct and evaluate its own leak tests, it shall establish procedures to be followed in leak testing sealed sources for possible leakage and contamination and submit a description of these procedures to the Commission. The description must include the—

(i) Instrumentation to be used;

(ii) Method of performing test; and

(iii) Pertinent experience of the person who will perform the test.

(2) If an applicant wants to use a leak test kit, it shall identify the manufacturer and the model number of the kit.

§ 39.15 Requirement for an agreement with well owner or operator.

(a) A licensee shall not perform well-logging with a sealed source unless it executes a written agreement with the well owner or operator, whichever engaged the licensee to perform the well-logging operation. The licensee shall retain a copy of the written agreement for 3 years after the completion of the well-logging operation.

(b) This written agreement must specify that:

(1) If a sealed source becomes lodged in the well, a reasonable effort will be made to recover it;

(2) A person may not attempt to recover a sealed source in a manner which, in the licensee's opinion, could result in its rupture;

(3) If the environment or if any equipment or personnel are contaminated with licensed material, they must be decontaminated before release from the site or release for unrestricted use; and

(4) If, after reasonable efforts at recovery have been expended, the sealed source is classified as irretrievable, the following requirements must be implemented within 30 days after a sealed source is classified as irretrievable:

(i) Each irretrievable well-logging source must be immobilized and sealed in place with a cement plug;

(ii) A whipstock or other deflection device must be set at some point in the well above the cement plug, unless the cement plug and source are not accessible to any subsequent drilling operations; and

(iii) A permanent identification plaque, constructed of long lasting material such as stainless steel, brass, bronze, or monel, must be mounted at the surface of the well, unless the mounting of the plaque is not practical. The size of the plaque must be at least 7-inches square and ⅛-inch thick. The plaque must contain—

(A) The word "CAUTION";

(B) The radiation symbol (the color requirement in § 20.203 of this chapter need not be met);

(C) The date the source was abandoned;

(D) The name of the well owner or well operator, as appropriate;

(E) The well name and well identification number(s) or other designation;

(F) An identification of the sealed source(s) by radionuclide and quantity;

(G) The depth of the source and depth to the top of the plug; and

(H) An appropriate warning such as "DO NOT RE-ENTER THIS WELL."

(c) A licensee may apply under § 39.91 for Commission case-by-case approval of proposed procedures to abandon an irretrievable well-logging source in a manner not otherwise authorized in paragraph (b)(4) of this section.

§ 39.17 Request for written statements.

Each license is deemed to contain the condition that the licensee will, at any time before expiration of the license, upon the Commission's request, submit written statements, signed under oath or affirmation, to enable the Commission to determine whether or not the license should be modified, suspended, or revoked.

Subpart C—Equipment Control

§ 39.31 Labels, security and transportation precautions.

(a) *Labels.* (1) The licensee may not use a source, source holder, or logging tool containing licensed material unless it bears a durable, legible, and clearly visible marking or label. The label must contain the radiation symbol specified in § 20.203 of this chapter, without the conventional color requirements, and the wording "DANGER (or CAUTION) RADIOACTIVE MATERIAL." The label must be on the smallest component that contains the licensed material transported as a separate piece of equipment.

(2) The licensee may not use a storage or transport container to store or transport licensed material unless it has permanently attached to it a durable, legible, and clearly visible label. The label must contain the radiation symbol, in conventional colors, and the wording "CAUTION (or DANGER), RADIOACTIVE MATERIAL, NOTIFY CIVIL AUTHORITIES (or NAME OF COMPANY)."

(b) *Security precautions during storage and transportation.* (1) The licensee shall store each source containing licensed material in a storage container or transportation package. The container or package must be locked and physically secured to prevent tampering or removal of licensed material from storage by unauthorized personnel. The licensee shall store licensed material in a manner which will minimize danger from explosion or fire.

(2) The licensee shall lock and physically secure the transport package containing licensed material to the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal of the licensed material from the vehicle.

(c) *Transportation precautions.* The licensee shall comply with the applicable provisions of the transportation regulations prescribed in Part 71 of this chapter. (Transportation of radioactive material is also subject to the Department of Transportation's regulations in 49 CFR Parts 171 through 178 which include provisions for proper packaging, marking and labeling, placarding of the transport vehicle, monitoring, accident reporting and for shipping papers.)

§ 39.33 Radiation detection instruments.

(a) The licensee shall keep a calibrated and operable radiation survey instrument at each field station and temporary jobsite to make the radiation surveys that are required by this part and by Part 20 of this chapter. To satisfy this requirement, the radiation survey instrument must be capable of measuring 0.1 milliroentgen per hour through at least 100 milliroentgens per hour. Survey instruments acquired before [one year after the effective date] and capable of measuring 0.1 milliroentgen per hour through at least 20 milliroentgens per hour also satisfy this requirement until [5 years after the effective date].

(b) the licensee shall have available additional calibrated and operable radiation detection instruments capable of detecting radiation and contamination levels that could be encountered during well-logging operations or in the event of an accident. The licensee may own the instruments or may arrange to obtain them from a second party.

(c) The licensee shall have each radiation survey instrument required under paragraph (a) of this section calibrated—

(1) At intervals not to exceed 6 months and after instrument servicing;

(2) At two points located approximately 1/3 and 2/3 of full scale on each scale (for logarithmic scale, at mid range of each decade, and at two points of at least one decade); and

(3) So that accuracy within plus or minus 20 percent of the true radiation level can be demonstrated on each scale.

(d) The licensee shall maintain calibration records for a period of 3 years after the date of calibration for inspection by the Commission.

§ 39.35 Leak testing of sealed sources.

(a) *Testing and recordkeeping requirements.* Each licensee using a sealed source shall have the source tested for leakage. The licensee shall keep a record of the leak test result in units of microcuries and maintain the record for inspection by the Commission for 3 years after the leak test is performed.

(b) *Method of testing.* A test for leakage must be performed only by a person specifically authorized by the Commission or an Agreement State to perform the test. The test sample must be taken from the nearest accessible point to the sealed source where contamination might accumulate. The test sample must be analyzed for radioactive contamination. The analysis must be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample.

(c) *Test frequency.* Each sealed source must be tested for leakage at intervals not to exceed 6 months. In the absence of a certificate from a transferor that a test has been made within the 6 months before the transfer, the sealed source may not be used until tested.

(d) *Removal of leaking source from service.* (1) If the test conducted pursuant to paragraph (a) and (b) of this section reveals the presence of 0.005 microcurie or more of removable radioactive material, the licensee shall remove the sealed source from service immediately and have it decontaminated, repaired, or disposed of by an NRC or Agreement State licensee that is authorized to perform these functions. The licensee shall check the equipment associated with the leaking source for radioactive contamination and, if contaminated, have it decontaminated or disposed of by an authorized licensee.

(2) The licensee shall file a report with the appropriate NRC Regional Office listed in Appendic D of Part 20 of this chapter, within 5 days of the test. The report must describe the equipment involved in the leakage, the test results, any contamination which resulted from the leaking source, and the corrective action taken.

(e) *Exemptions from testing requirements:* The following sealed sources are exempt from periodic leak test requirements in paragraphs (a) through (d) of this section:

(1) Hydrogen-3 sources;

(2) Sources containing licensed material with a half-life of 30 days or less;

(3) Sealed sources containing licensed material in gaseous form;

(4) Sources of beta- and/or gamma-emitting radioactive material with an activity of 100 microcuries or less; and

(5) Sources of alpha-emitting radioactive material with an activity of 10 microcuries or less.

§ 39.37 Physical inventory.

Each licensee shall conduct a semiannual physical inventory to account for all licensed material received and possessed under the license. The licensee shall maintain records of the inventory for 3 years from the date of the inventory for inspection by the Commission. The inventory must indicate the quantity and kind of licensed material, location of the licensed material, the date of the inventory, and the name of the individual conducting the inventory.

§ 39.39 Utilization records.

(a) Each licensee shall maintain a record showing the following information for each utilization of licensed material:

(1) The make, model number, and a serial number or a description of each sealed source used;

(2) In the case of a radioactive marker or unsealed licensed material used for subsurface tracer studies, the radionuclide and quantity of activity used in a particular well;

(3) The identity of the logging supervisor and logging assistants to whom the licensed material is assigned; and

(4) Location and date of use of the licensed material.

(b) The licensee shall maintain the records required by paragraph (a) of this section available for inspection by the Commission and shall retain the record for 3 years from the date of the recorded event.

§ 39.41 Design and performance criteria for sealed sources.

(a) A licensee may not use a sealed source, except one containing licensed material in gaseous form, manufactured after [one year after the affective date of the final rule] in well-logging unless the manufacturer certifies to licensee that the sealed source meets the following criteria:

(1) It is doubly encapsulated construction;

(2) It contains licensed material whose chemical and physical forms are as insoluble and non-dispersible as practical;

(3) It has individually passed pressure testing to 24,600 pounds per square inch absolute without leakage; and

(4) It meets the following performance requirements by prototype testing. Compliance with the tests is determined by the ability of the protoype to maintain its integrity after each of the following tests:

(i) *Temperature*—the test source must be held at −40°C for 20 minutes, 600°C for 1 hour, and then be subject to a thermal shock test with a temperature drop from 600°C to 20°C within 15 seconds;

(ii) *Impact test*—a 5 kg steel hammer, 2.5 cm in diameter, must be dropped from a height of 1 m onto the test source;

(iii) *Vibration test*—the test source must be subject to a vibration from 25 Hz to 500 Hz at 5 g amplitude for 30 minutes; and

(iv) *Puncture test*—a 1 gram hammer and pin, 0.3 cm pin diameter, must be dropped from a height of 1 m onto the test source.

(b) After [2 years after the effective date of this rule], a licensee may not use a sealed source manufactured before [one year after the effective date of this rule], except one containing licensed material in gaseous form, unless the manufacturer, or a qualified testing organization, certifies to the licensee that the sealed source meets:

(1) The criteria of paragraphs (a)(1), (a)(2), and (a)(3) of this section; or

(2) The criteria of paragraphs (a)(1), (a)(2), (a)(3) of this section by prototype test, and the performance requirement of paragraph (a)(4) of this section.

(c) The licensee shall keep the certification documents described by paragraphs (a) and (b) of this section for inspection by the Commission for 3 years after transfer or disposal of the source or its abandonment in a well.

§ 39.43 Inspection, maintenance, and opening of a source or source holder.

(a) Each licensee shall inspect the source holders, logging tools, and source handling tools for obvious defects before the equipment is used each day to ensure that the equipment is in good working condition.

(b) Each licensee shall conduct a program of visual inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers, injection tools, and sinker bars to ensure that the required labeling is legible and that visual physical damage is absent. The licensee shall perform the visual inspection and maintenance at least every 6 months. The licensee shall maintain records of inspection and maintenance for 3 years for inspection by the Commission.

(c) If the inspection conducted under paragraph (a) of this section reveals damage to the labeling or to components critical for radiation safety, the licensee shall remove the item from service until repairs are made.

(d) Removal of a sealed source from a source holder, and maintenance on sealed sources, holders or pressure housings in which sealed sources are placed, or on other equipment containing a sealed source may not be performed unless a written instruction has been approved by the Commission as part of the license application.

(e) If a sealed source is stuck in the source holder or logging tool, the licensee may not perform any operation, such as drilling, cutting, or chiseling, on the source holder or logging tool, unless it is specifically licensed by the Commission to perform this operation.

(f) The repair, opening, or modification of any sealed source must be performed only by persons specifically licensed to do so by the Commission.

§ 39.45 Subsurface tracer studies.

(a) The licensee shall require all personnel handling radioactive tracer material to use protective gloves and clothing and other appropriate equipment. The licensee shall take precautions to avoid ingestion or inhalation of radioactive trace material and to avoid contamination of field stations and temporary jobsites. (Bioassay services may be required by § 39.65(b).)

(b) A licensee may not inject licensed material into fresh water aquifers unless specifically authorized to do so by the Commission.

§ 39.47 Radioactive markers.

The licensee may not use a radioactive marker in wells, unless the individual marker contains quantities of licensed material not exceeding the specified quantities in § 30.71 of this chapter.

§ 39.49 Uranium sinker bars.

The licensee may not use a uranium sinker bar in well-logging operations after [one year from the effective date of the rule], unless it is legibly impressed with the words "CAUTION-RADIOACTIVE-DEPLETED URANIUM" and "NOTIFY CIVIL AUTHORITIES [or COMPANY NAME] IF FOUND."

§ 39.51 Use of a sealed source in a well without surface casing.

The licensee may not use a sealed source in a well without a surface casing designed to protect fresh water aquifer zones, unless procedures for protecting these zones are specifically approved by the Commission.

Subpart D—Radiation Safety Requirements

§ 39.61 Training.

(a) The licensee may not permit an individual to act as a logging supervisor until that person:

(1) Has completed at least 40 hours of formal training in the subjects outlined in paragraph (e) of this section;

(2) Has received copies of and instruction in:

(i) NRC regulations contained in this part and in the applicable section of Parts 19, 20, 21, 30, 40, 70, and 71 of this chapter;

(ii) The NRC license under which the logging supervisor will perform well-logging operations; and

(iii) The licensee's operating, recordkeeping, and emergency procedures;

(3) Has completed 3 months of on-the-job training and demonstrated competence in the use of licensed materials, remote handling tools, and radiation survey instruments by a field evaluation; and

(4) Has demonstrated understanding of the requirements in paragraphs (a) (1) and (2) of this section by successfully completing a written test.

(b) The licensee may not permit an individual to act as a logging assistant until that person:

(1) Has received instruction in applicable sections of Parts 19, 20, and 21 of this chapter;

(2) Has received copies of and instruction in the licensee's operating and emergency procedures;

(3) Has demonstrated uderstanding of the materials listed in paragraphs (b) (1) and (2) of this section by successfully completing a written or oral test; and

(4) Has received instruction in the use, under the personal supervision of the logging supervisor, of tracer material, sealed sources, remote handling tools, and radiation survey instruments.

(c) The licensee shall provide for the annual retraining of logging supervisors and logging assistants.

(d) The licensee shall maintain a record of each logging supervisor's and logging assistant's training, including copies of written tests and dates of oral tests, for 3 years following the termination of employment.

(e) The licensee shall include the following subjects in the formal training required in paragraph (a)(1) of this section:

(1) Fundamentals of radiation safety:

(i) Characteristics of radiation;

(ii) Units of radiation dose and quantity of radioactivity;

(iii) Hazards of exposure to radiation;

(iv) Levels of radiation from licensed material;

(v) Methods of controlling radiation dose:

(A) Working time;

(B) Working distances;

(C) Shielding;

(vi) Radiation safety practices, including prevention of contamination, and methods of decontamination;

(2) Radiation detection instrumentation to be used:

(i) Use of radiation survey instruments:

(A) Operation;

(B) Calibration;

(C) Limitations;

(ii) Survey techniques;

(iii) Use of personnel monitoring equipment;

(3) Equipment to be used:

(i) Handling equipment and remote handling tools:

(ii) Licensed materials;

(iii) Storage, control, and disposal of equipment and licensed material;

(iv) Operation and control of equipment and licensed materials;

(v) Maintenance of equipment;

(4) The requirements of pertinent Federal and State regulations; and

(5) Case histories and potential consequences of accidents in well-logging operations.

§ 39.63 Operating and emergency procedures.

Each licensee shall develop and follow written operating and emergency procedures that cover instruction in—

(a) The handling and use of licensed materials to be employed so that no individual is likely to be exposed to radiation doses in excess of the limits established in Part 20 of this chapter;

(b) Methods and occasions for conducting radiation surveys;

(c) Methods and occasions for locking and securing licensed materials;

(d) Personnel monitoring and the use of personnel monitoring equipment;

(e) Transportation of licensed materials to field stations or temporary jobsites, including packing of licensed materials in vehicles, placarding of vehicles when needed, and physically securing licensed materials to transport vehicles during transportation to prevent accidential loss, tampering, or unauthorized removal;

(f) Minimizing personnel exposure, including that from inhalation and ingestion of licensed materials, during well-logging operations and in the event of an accident;

(g) The procedure for notifying proper persons in the event of an accident;

(h) Maintenance of records;

(i) The inspection of maintenance of source holders, logging tools, source handling tools, storage containers, transport containers, and injection tools;

(j) The procedure to be followed if a sealed source is lodged in a well or ruptured;

(k) The procedure to be used for picking up, receiving, and opening packages containing licensed materials;

(l) The procedure for identifying and reporting to NRC defects and noncompliance, as required by Part 21 of this chapter;

(m) The procedure and the use of tools for remote handling of sealed sources and radioactive tracer material, except low-activity calibration sources;

(n) The procedure to be used for detecting contamination, required by §§ 39.67(c) through (e), and for preventing the spread of contamination; and

(o) The procedure to be used to decontaminate the environment, equipment or personnel if any or all are contaminated.

§ 39.65 Personnel monitoring.

(a) The licensee may not permit an individual to act as a logging supervisor or logging assistant unless that person wears, at all times during well-logging operations, either a film badge or a thermoluminescent dosimeter (TLD). Each film badge or TLD must be assigned to and worn by only one individual. The film badge must be replaced at least monthly and TLD badges replaced at least quarterly. The licensee shall have each badge or dosimeter processed.

(b) The licensee shall provide appropriate bioassay services to individuals using licensed materials in subsurface tracer studies.

(c) The licensee shall keep reports received from the badge or TLD processor and from the bioassay service laboratory for inspection until the Commission authorizes disposition or terminates the license.

§ 39.67 Radiation surveys.

(a) The licensee shall make radiation surveys, including but not limited to paragraphs (b) through (e) of this section, of each area where licensed materials are used and stored.

(b) Before transporting the licensed materials, the licensee shall make a radiation survey of the position occupied by each individual in the vehicle and of the exterior of each vehicle used to transport the licensed materials.

(c) After removing the sealed source assembly from the logging tool and before departing from the temporary jobsite, the licensee shall confirm that the logging tool is free of contamination by energizing the logging tool detector or by using a survey meter.

(d) If the licensee suspects that, as a result of operations involving a sealed source, the encapsulation of the sealed source could be damaged by the operation, it shall conduct a radiation survey, including a contamination survey, during and after the operation.

(e) The licensee shall make a radiation survey at the temporary jobsite for each subsurface tracer study. The survey must include a measurement of radiation levels before and after the operation, and a measurement of contamination levels after the subsurface tracer study.

(f) The results of surveys required under paragraphs (a) through (e) of this section must be recorded and must include the date the survey took place, the name of the individual making the survey, the identification of the survey instrument used, and the location of the survey. The licensee shall maintain records of surveys for inspection by the Commission for 3 years after they are made.

§ 39.69 Radioactive contamination control.

(a) During efforts to recover a sealed source lodged in the well, the licensee shall continuously monitor, with an appropriate radiation detection instrument or a logging tool with a radiation detector, the circulating fluids from the well to check for contamination resulting from damage to the sealed source.

(b) If the licensee detects evidence that the sealed source has ruptured or licensed materials have caused contamination, it shall initiate the emergency procedures required by § 39.63 immediately.

(c) If contamination results from the use of licensed material in well-logging operations, the licensee shall decontaminate all work areas, equipment, and unrestricted areas.

Subpart E—Security, Records, Notifications

§ 39.71 Security.

During each well-logging operation, the logging supervisor or other licensee employee designated by the logging supervisor shall maintain direct surveillance of the operation to prevent unauthorized entry into a restricted area, as defined in § 20.3(a)(14) of this chapter.

§ 39.73 Documents and records required at field stations.

(a) Each licensee shall maintain the following documents and records at the field station:

(1) A copy of applicable NRC regulations;

(2) The license authorizing the use of licensed material;

(3) Operating and emergency procedures;

(4) The record of the radiation survey instrument calibration required by § 39.33;

(5) The record of the leak test results required by §39.35;

(6) Physical inventory records required by § 39.37;

(7) Utilization records required by § 39.39;

(8) Records of inspection and maintenance required by § 39.43;

(9) Training records required by § 39.61(d); and

(10) Survey records required by § 36.67.

(b) Records required by paragraphs (a)(1) through (3) of this section must be kept until the licensee terminates its well-logging operations at the field station. Records required by paragraphs (a)(4) through (10) of this section must be kept for 3 years.

§ 39.75 Documents and records required at temporary jobsites.

Each licensee conducting operations at a temporary jobsite shall maintain the following documents and records at the temporary jobsite until the well-logging operation is completed:

(a) Operating and emergency procedures;

(b) Evidence of latest calibration of the radiation survey instruments in use at the site required by § 39.33;

(c) Latest survey records required by § 39.67;

(d) The shipping papers for the transportation of radioactive materials required by § 71.5 of this chapter; and

(e) A copy of the NRC license authorizing use of licensed materials, or a copy of the Agreement State license when operating under reciprocity pursuant to § 150.20 of this chapter.

§ 39.77 Notification of incidents and lost sources; abandonment procedures for irretrievable sources.

(a) The licensee shall immediately notify the appropriate NRC Regional Office by telephone and subsequently within 5 days by confirmatory letter if it knows or has reason to believe that (1) licensed material has been lost in or near a fresh water aquifer; or (2) a sealed source has been ruptured. This notice must designate the well or other location and describe the magnitude and extent of licensed materials, assess the consequences of the loss or rupture, and explain efforts planned or being taken to mitigate these consequences.

(b) The licensee shall notify the Commission of incidents and sources lost, other than in the well, in accordance with §§ 20.402, 20.403, and 20.405 of this chapter.

(c) If a sealed source becomes lodged in a well, and when it becomes apparent that efforts to recover the sealed source will not be successful, the licensee shall—

(1) Advise the well owner or operator, as appropriate, of the abandonment procedures under § 39.15 (b) or (c) and ensure that these procedures are implemented within 30 days after the sealed source has been classified as irretrievable; and

(2) Notify the appropriate NRC Regional Office by telephone of the circumstances of the loss, and request approval to implement abandonment procedures.

(d) The licensee shall, within 30 days after a sealed source has been classified as irretrievable, make a report in writting to the appropriate NRC Regional Office. The licensee shall send a copy of the report to each appropriate State agency that has authority over the particular well-drilling operation. The report must contain the following information:

(1) Date of occurrence;

(2) A description of the irretrievable well-logging source involved, including radionuclide, quantity, chemical and physical form;

(3) Surface location and identification of the well;

(4) Results of efforts to immobilize and seal the source in place;

(5) Depth of the source;

(6) Depth of the top of the cement plug;

(7) Depth of the well;

(8) Any other information (e.g., warning statement) contained on the permanent identification plaque;

(9) Notifications made to State agencies; and

(10) A brief description of the attempted recovery effort.

Subpart F—Exemptions

§ 39.91 Applications for exemptions.

The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

Subpart G—Enforcement

§ 39.101 Violations.

(a) An injunction or other court order may be obtained to prohibit a violation of any provision of this part.

(b) A court order may be obtained for the payment of a civil penalty imposed for violation of this part.

(c) Any person who willfully violates any provision of this part issued under section 161 b., i., or o. of the Atomic Energy Act of 1954, as amended, or the provisions cited in the authority citation at the beginning of this part may be guilty of a crime and, upon conviction, may be punished by fine or imprisonment, or both, as provided by law.

PART 19—NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS; INSPECTIONS

§ 19.2 [Amended]

2. Section 19.2 is amended by adding "39," after "Parts 30 through 35," in the first sentence.

§ 19.3 [Amended]

3. Section 19.3(d) is amended by adding "39," after "Parts 30 through 35," in the first sentence.

PART 20—STANDARDS FOR PROTECTION AGAINST RADIATION

§ 20.2 [Amended]

4. Section 20.2 is amended by adding "39," after "Parts 30 through 35," in the first sentence.

§ 20.3 [Amended]

5. Section 20.3(a)(9) is amended by adding "39," after "Parts 30 through 35," in the first sentence.

PART 21—REPORTING OF DEFECTS AND NONCOMPLIANCE

§ 21.2 [Amended]

6. Section 21.2 is amended by adding "39," after "34, 35," in the first sentence.

PART 30—RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

§ 30.4 [Amended]

7. In §30.4, paragraph (b) and (i) are amended by adding "and 39" after "31 through 35", and paragraph (x) is removed.

§ 30.5 [Amended]

8. Section 30.5 is amended by adding "and 39" after "31 through 35".

§ 30.6 [Amended]

9. In § 30.6, paragraph (b)(1) is amended by adding "39" after "30 through 35" in the first sentence.

§ 30.11 [Amended]

10. In § 30.11, paragraph (a) is amended by adding "and 39" after "31 through 35".

§ 30.13 [Amended]

11. Section 30.13 is amended by adding "and 39" after "31 through 35".

§ 30.14 [Amended]

12. In § 30.14, paragraph (a) is amended by adding "and 39" after "31 through 35" and paragraph (c) is amended by removing "and 34" and adding "34 and 39" after "32, 33".

§ 30.15 [Amended]

13. In § 30.15, paragraph (a) is amended by adding "and 39" after "31 through 35".

§ 30.18 [Amended]

14. In § 30.18, paragraph (a) is amended by adding "and 39" after "30 through 34".

§ 30.31 [Amended]

15. Section 30.31 is amended by adding "and 39" after "32 through 35".

§ 30.33 [Amended]

16. Section 30.33, paragraph (a)(4) is amended by adding "and 39" after "32 through 35".

§ 30.34 [Amended]

17. Section 30.34, paragraph (a) and (b) are amended by adding "and 39" after "31 through 35"; paragraph (c) is amended by adding "and 39" after "31 through 35" in the first and the second sentences; paragraphs (d) and (e) are amended by adding "and 39" after "31 through 35".

§ 30.39 [Amended]

18. Section 30.39 is amended by adding "and 39" after "32 through 35".

§ 30.56 [Removed]

19. Section 30.56 is removed.

PART 40—DOMESTIC LICENSING OF SOURCE MATERIAL

§ 40.5 [Amended]

20. In § 40.5, paragraph (b)(1) is amended by adding "39," after "30 through 35," in the first sentence.

PART 51—ENVIRONMENTAL REGULATIONS FOR DOMESTIC LICENSING AND RELATED REGULATORY FUNCTIONS

§ 51.22 [Amended]

21. In § 51.22, paragraphs (c)(3), (c)(10) and (c)(14) are amended by adding "39," after "34, 35," in the first sentence of each paragraph.

PART 70—DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

§ 70.4 [Amended]

22. In § 70.4, paragraph (w) is removed.

§ 70.5 [Amended]

23. In § 70.5, paragraph (b)(1) is amended by adding "39" after "30 through 35."

§ 70.60 [Removed]

24. Section 70.60 is removed.

PART 71—PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

§ 71.0 [Amended]

25. In § 71.0, paragraph (b) is amended by adding "39," after "21, 30," in the first sentence.

PART 150—EXEMPTIONS AND CONTINUED REGULATORY AUTHORITY IN AGREEMENT STATES AND IN OFFSHORE WATERS UNDER SECTION 274

§ 150.20 [Amended]

26. In § 150.20, paragraph (b) is amended by removing "70.60, to 70.62, inclusive," and adding "70.61, 70.62," after "70.51 to 70.56, inclusive,"; and by adding "§ 39.15 and Subparts C, D, E, F, and G of Part 39" after "and to the provisions of Parts 19, 20, and 71" of the first sentence.

The conforming amendments to Parts 19, 20, 21, 30, 40, 51, 70, 71, and 150 are issued under the following authority:

(Sec. 161, Pub. L. 83–703, 68 Stat. 948, as amended (42 U.S.C. 2201); sec. 201, Pub. L. 93–438, 82 Stat. 1242, as amended (42 U.S.C. 5841))

Dated at Washington, D.C. this 2nd day of April, 1985.

For the Nuclear Regulatory Commission.

John C. Hoyle,

Acting Secretary of the Commission.

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